NOTE

This Microfiche meets the quality requirements of the American National Standard for Microfiche of Documents (ANSI PH5.9-1975). However, because of imperfections in the document from which it was made, it contains images that are illegible or difficult to read. The source document for this microfiche is the best copy that could be obtained prior to filming.

CIS Congressional Information Service, Inc
Washington, D.C.

H.R. 4192, THE RISK ASSESSMENT RESEARCH AND DEMONSTRATION ACT OF 1983

HEARINGS

BEFORE THE

SUBCOMMITTEE ON NATURAL RESOURCES,
AGRICULTURE RESEARCH AND ENVIRONMENT

OF THE

COMMITTEE ON
SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

NINETY-EIGHTH CONGRESS

SECOND SESSION

MAY 17; JUNE 5, 1984

[No. 145]

Printed for the use of the
Committee on Science and Technology

U.S. GOVERNMENT PRINTING OFFICE
40-299 O WASHINGTON : 1985

H701-67

COMMITTEE ON SCIENCE AND TECHNOLOGY

DON FUQUA, Florida, *Chairman*

ROBERT A. ROE, New Jersey
GEORGE E. BROWN, Jr., California
JAMES H. SCHEUER, New York
RICHARD L. OTTINGER, New York
TOM HARKIN, Iowa
MARILYN LLOYD, Tennessee
DOUG WALGREN, Pennsylvania
DAN GLICKMAN, Kansas
ALBERT GORE, Jr., Tennessee
ROBERT A. YOUNG, Missouri
HAROLD L. VOLKMER, Missouri
BILL NELSON, Florida
STAN LUNDINE, New York
RALPH M. HALL, Texas
DAVE McCURDY, Oklahoma
MERVYN M. DYMALLY, California
PAUL SIMON, Illinois
NORMAN Y. MINETA, California
RICHARD J. DURBIN, Illinois
MICHAEL A. ANDREWS, Texas
BUDDY MacKAY, Florida
TIM VALENTINE, North Carolina
HARRY M. REID, Nevada
ROBERT G. TORRICELLI, New Jersey
FREDERICK C. BOUCHER, Virginia

LARRY WINN, Jr., Kansas
MANUEL LUJAN, Jr., New Mexico
ROBERT S. WALKER, Pennsylvania
WILLIAM CARNEY, New York
F. JAMES SENSENBRENNER, Jr., Wisconsin
JUDD GREGG, New Hampshire
RAYMOND J. McGRATH, New York
JOE SKEEN, New Mexico
CLAUDINE SCHNEIDER, Rhode Island
BILL LOWERY, California
ROD CHANDLER, Washington
HERBERT H. BATEMAN, Virginia
SHERWOOD L. BOEHLERT, New York
ALFRED A. (AL) McCANDLESS, California
TOM LEWIS, Florida

Harold P. Hanson, *Executive Director*
Robert C. Ketcham, *General Counsel*
Regina A. Davis, *Chief Clerk*
David S. Jeffery, *Minority Staff Director*

Subcommittee on Natural Resources, Agriculture Research and Environment

JAMES H. SCHEUER, New York, *Chairman*

TIM VALENTINE, North Carolina
TOM HARKIN, Iowa
MICHAEL A. ANDREWS, Texas
BUDDY MacKAY, Florida
ROBERT G. TORRICELLI, New Jersey
GEORGE E. BROWN, Jr., California

RAYMOND J. McGRATH, New York
CLAUDINE SCHNEIDER, Rhode Island
ROD CHANDLER, Washington
TOM LEWIS, Florida

CONTENTS

WITNESSES

May 17, 1984: Page
- Hon. Don Ritter, a U.S. Representative from the State of Pennsylvania 3
- Dr. Nicholas Ashford, director, Center for Policy Alternatives, Massachusetts Institute of Technology; Dr. Joseph Rodricks, Environ Corp.; and Dr. Peter Huber, law clerk, U.S. Supreme Court 20
- Dr. Michael Jacobson, executive director, Center for Science in the Public Interest; accompanied by Bruce Silverglade, legal director 105
- Dr. Linda Randolph, New York State Department of Public Health 122

June 5, 1984:
- Hon. Richard Ottinger, a U.S. Representative from the State of New York 130
- Dr. Sanford Miller, Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration; Dr. Bernard D. Goldstein, Assistant Administrator for Research and Development, Environmental Protection Agency; Dr. Peter W. Preuss, Associate Executive Director for Health Sciences, Consumer Product Safety Commission; and Dr. R. Leonard Vance, Director, Health Standards Programs, Occupational Safety and Health Administration 141
- Frances Dubrowski, Esq., senior staff attorney, Natural Resources Defense Council, accompanied by Dr. Karim Ahmed; Dr. Paul F. Deisler, Jr., vice president, American Industrial Health Council; Dr. David L. Mallino, Industrial Union Department, accompanied by Sheldon Samuels; John J. Sheehan, legislative director, United Steelworkers of America 166
- Dr. Richard Wilson, chairman, Department of Physics, Harvard University and David Sive, Esq., Winer, Newberger & Sive 215

APPENDIX

Additional Materials for the Record

1. H.R. 4192, the "Risk Assessment Research and Demonstration Act of 1983". 225
2. Additional materials submitted by Dr. David L. Mallino, Industrial Union Department, AFL-CIO 247
3. Letter from the National Academy of Sciences 286
4. Submissions from:
   - a. Environmental Protection Agency (EPA) 289
   - b. Occupational Safety and Health Administration (OSHA) 402
   - c. Consumer Product Safety Commission (CPSC) 425
   - d. Food and Drug Administration (FDA) 430
   - e. Food Safety and Inspection Service (FSIS), Department of Agriculture ... 444

H.R. 4192, THE RISK ASSESSMENT RESEARCH AND DEMONSTRATION ACT OF 1983

THURSDAY, MAY 17, 1984

HOUSE OF REPRESENTATIVES, COMMITTEE ON SCIENCE AND
TECHNOLOGY, SUBCOMMITTEE ON NATURAL RESOURCES,
AGRICULTURE RESEARCH AND ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:44 a.m., in room 2318, Rayburn House Office Building, Hon. James Scheuer (chairman of the subcommittee) presiding.

Present: Representatives Scheuer, Valentine, McGrath, and Schneider.

Mr. SCHEUER. Good morning. The Subcommittee on Natural Resources, Agriculture Research, and Environment will come to order.

Today we will hear from a distinguished group of witnesses on the subject of risk assessment and the bill sponsored by our colleague, Mr. Ritter, of Pennsylvania on the subject of risk assessment. This whole area of risk assessment is a subject that has become increasingly important as our understanding of the pervasiveness of hazards throughout our environment grows.

Risk assessment, of course, is the process by which we try to determine the human health effects of exposures to various carcinogens and other toxic substances in the environment. A sophisticated and reasonably thoughtful risk-assessment process can tell us whether a particular substance is harmful and how harmful, and it can attempt to help us gauge how serious the risk is.

Only after we know the extent of the hazard posed by a particular substance can we make an intelligent decision about whether we are going to regulate it and how we are going to regulate it. Given the often controversial nature of regulatory decisions concerning health hazards of all kinds, it is not astonishing that the risk assessments used to support these decisions have drawn their share of criticism. Critics have charged that attempts to measure risk scientifically have often been biased by the introduction of political, economic, and social values that distort the conclusion.

Today, we will be considering title I of H.R. 4192, the Risk Analysis Research and Demonstration Act. Congressman Martin, we are told, intends to withdraw title II, and we therefore do not address that part of the bill today. Title I is the latest version of an effort begun by Congressman Don Ritter, my distinguished colleague from Pennsylvania, back in 1979, to address some of the criticisms of risk assessment as it is carried on today.

The version we will consider today would require at least eight Federal agencies to conduct demonstration risk-assessment projects under the coordination of an agency to be designated by the President. The coordinating agency would report back to Congress on the results of the projects and make recommendations to the Congress. The bill also sets out criteria to be included in the demonstration risk assessments.

As we consider the testimony today and on June 5, we would do well to temper our expectations. As the prestigious National Academy of Sciences recently warned in a comprehensive report on risk assessment: "Because risk assessment is only one aspect of risk management decisionmaking, however, even greatly improved assessments will not eliminate dissatisfaction with risk management decisions."

Further, the unavoidable fact is that science still has a great deal to learn about the human-health effects of most chemical substances and a great deal to learn about how we measure them and how we evaluate them. For the foreseeable future, the decision whether or not to regulate will continue to be made against a backdrop of pervasive uncertainty and less than full and adequate data.

The National Academy of Sciences report also observed that the process of risk assessment has been developing rapidly in recent years. We hope to hear more about these recent developments in the next 2 days of hearings. I note, for example, that Mr. Ruckelshaus, the Administrator of the EPA, has launched a new program at EPA for risk assessment and has taken the lead in putting together a new interagency group to coordinate the development of risk-assessment processes and procedures.

We have a number of distinguished witnesses with us today, some of whom are under time pressures. I am delighted to welcome as the first witness one of our colleagues who is most conversant and most sophisticated in his knowledge of science and technology and has done perhaps as much profound thinking on this subject as any other Member of Congress. As a former member of this committee, Congressman Don Ritter has been a leading force in focusing our attention on the use of risk assessment in Federal agencies, and I want to congratulate him for the great leadership he has shown in the last few years and to welcome him to the committee today.

Don, we look forward to your testimony, and after you testify, I hope you will come up here and join me to the extent that you have the time.

I know that at 10 a.m., our Subcommittee on Health and Environment, on which we both serve, is considering the smoking bill which is where we are going to mark the cigarette packages with four elements of early warning signals, so to speak. Since this, in effect, is a risk assessment and is right up your alley, I know how deeply concerned you are with that, as I am, and it may be that you will want to disappear for a few minutes and go down and perhaps represent both of us at that hearing. However, to the extent that you have time, we would be delighted to have you come up here and share the challenge of questioning our witnesses.

STATEMENT OF HON. DON RITTER, A U.S. REPRESENTATIVE FROM THE STATE OF PENNSYLVANIA

Mr. RITTER. I thank the chairman for his generous introduction. I thank him for his previous cosponsorship of several of my risk bills which have along the way, I think, been modified and refined in trying to approach the problem in the most intelligent way. It is a difficult one. It has turned into a somewhat controversial one. We admit that, but we are moving ahead in the attempt to try to find some consensus in this most important area.

How a nation puts hazards in perspective is very important because it impacts not just on the esoteric regulatory processes deep in the backrooms of a Federal agency, but it really impacts on what energy sources a nation is able to promote. It really impacts on jobs in industrial America in a variety of manufacturing industries from chemical industries, to steel industries, to autos. It really impacts on the way we intelligently seek to reduce the health hazards to American workers in the workplace, American citizens driving cars, Americans who have to breathe the air and drink the water. It is quite an all encompassing view.

My whole approach over the years has been to try to inject where possible a greater modicum of science into that process. Since so many of these eventually standard setting procedures are technological and scientific at their roots, I have felt that to inject some greater degree of science into that process would be most helpful to the regulators and to the society who have to make these often difficult decisions. In no way have I envisioned that the technique of risk assessment, and risk comparison, and analyzing hazards, and putting them into perspective would supplant or replace the basic social, economic, political decisions that eventually constitute a final regulatory decision.

I felt that in the toolbox that the regulators brought to the process, some more science, some better science, was necessary. I have worked very closely over the years with my colleagues on this committee, when I served on this committee the original bills had major cosponsorship on the Science and Technology Committee. I felt that the Science and Technology Committee was the place to make the basic inroads into this field, because more than any other committee, it has a degree of cooperation, and consensus, and bipartisanship and a kind of scientific approach to issues which, frankly, is lacking in some of the other more highly politicized, partisan committees. The chairman and I are both familiar with the committees in question here.

It is important that these hearings are being held and that we attempt to move forward in this area.

Mr. Martin of North Carolina, about 1 year ago, injected into this legislation a level of discussion heretofore absent by creating a new title which brought a great deal of controversy. It talked about a major risk assessment board that would be composed of risk-assessment czars. On critical key issues, they would have a kind of bureaucratic intervention. Their recommendation would be quasi-law. That ran into many, many difficulties and, frankly, I believe that at best that title II argument was somewhat premature. We are no longer encumbered by title II.

Title I is a refinement of a legislative vehicle which started, as the chairman mentioned, in 1979, and has been refined until the present date in 1984. It has undergone 5 years of refinement. It passed the House under suspension in a probably less refined state in the last Congress. It went through subcommittee and committee in the Senate and died in the closing day of the lameduck session of the Senate in the last Congress. It had something to do with the key committee chairman on that side being involved in a major, political contest. So, we came back in this Congress and we came back with an additional title that has slowed the bill down.

I want to set the stage here because we have been working on this for a long time and, as I mentioned, the chairman has been a cosponsor of previous legislative vehicles, that which did not include this new and more sweeping title.

I am hopeful that this subcommittee will take quick action, that we can move on this legislation in this Congress. There is a real need to bring the subject of risk assessment, and risk comparison, and putting hazards in perspective down from the academic and the more technical mountain. I am convinced that we need to work very hard to allow the nontechnical community to understand the value of risk assessment and the insights that it can provide.

It is beginning to mature as a science, perhaps quasi-science. It has a long way to go, but I submit that we, as individuals, as citizens, every day are performing unconscious risk assessments, sometimes even conscious risk assessments as we light up or do not light up a cigarette, as we eat or do not eat a big slab of beef with a large marble of fat, as we cross a street, as we drive a car, as we fly an airplane, as we hang glide, as we rock climb. It is all part of our lives. It is not something that is that esoteric. What we are trying to do is work toward some quantification of what we do naturally in areas which are more scientific, more technical, or more difficult in which to make these kinds of critical choices. So, we say let's offer this as an assist, as an aid, as a tool in the regulatory toolbox, not as a series circuit or in-line hurdle that must be passed prior to making regulatory decisions.

Title I of H.R. 4192 seeks to authorize an organized research and development effort within our Federal agencies in order to develop risk assessment and risk comparison techniques and their use. The Environmental Protection Agency has already seen the need for interagency comparison of such assessment methodology and is establishing presently protocols for pooling the Agencies' resources.

On another front, the National Academy of Sciences published a comprehensive study entitled "Risk Assessment in the Federal Government." In its report, the Academy made the following recommendations: An agency should prepare a detailed and comprehensive risk assessment prior to its decision to regulate a substance as a health hazard.

I am not even saying that it should. I think it could and it might derive benefit if it does, but the Academy said that it should.

The Academy says that when formulating a risk assessment, an agency should use a consistent format and establish uniform guidelines to foster more efficient use and to encourage better public understanding. Joint risk assessments should be encouraged when two or more agencies share interest in the jurisdiction over a candidate health hazard. Risk assessment should not embody any influence from risk management. The two processes must be clearly delineated. Risk assessment guidelines should be comprehensive, detailed, and flexible and should make explicit distinctions between the science and the policy aspects.

All of this, our bill, H.R. 4192, attempts to do. It provides a framework, the legislative side, for carrying out some of the recommendations of the National Academy of Sciences study.

In the light of the kind of large budget deficits that we face, in the light of the limited resources that our agencies have, in the light of the at times massive public outcry, media sensation, politicizing of critical health, environment, and safety issues, it is essential that we have a slightly greater science base in approaching these problems.

Title I of H.R. 4192 is an important step in the effort to identify those hazards that pose the most significant risks to our human life, to our human health, to our environment. We can't handle all of them with finite resources. There has to be, at some stage, the setting of priorities, and that is what H.R. 4192 seeks as a kind of eventual goal. We will be healthier, we will live longer, and we will make better use of our limited, scarce, regulatory resources if we do this. By identifying the significance of risk as a factor, our citizens can make more rational decisions in an ever increasing technological society, a society ever more exposed to what the risks and hazards of living in a technological society may be. They can better understand the significance of choosing between alternative risks.

We have so many cases, whether it is in food, in worker safety, in energy, or just basic personal products and consumer products. We will all benefit by greater science in the process.

I would like to say that title I does not modify any existing regulatory statutes through the vehicle of H.R. 4192. The agencies are simply encouraged to pool resources, to communicate, to develop consistent methodologies that will yield mutually important and useful data for understanding these hazards. The legislation does not deal with the management aspects of risk. It is an assessment, a comparison tool. It is not a management bill.

I would like to have read into the record at this point an article by Dr. Bruce Ames.

Mr. SCHEUER. Without objection, so ordered.

Mr. RITTER. I thank the chairman.

It is an article by Dr. Bruce Ames who is chairman of the biochemistry department at the University of California at Berkeley. It was published in Science Magazine September 23, 1983. It has 183 references, and it is a very significant article in the context of what we are talking about today. It is entitled "Dietary Carcinogens and Anticarcinogens."

[Article by Dr. Ames follows:]

6

Dietary Carcinogens and Anticarcinogens

Oxygen radicals and degenerative diseases

Bruce N. Ames

Summary. The human diet contains a great variety of natural mutagens and carcinogens, as well as many natural antimutagens and anticarcinogens. Many of these mutagens and carcinogens may act through the generation of oxygen radicals. Oxygen radicals may also play a major role as endogenous initiators of degenerative processes, such as DNA damage and mutation (and promotion), that may be related to cancer, heart disease, and aging. Dietary intake of natural antioxidants could be an important aspect of the body's defense mechanism against these agents. Many antioxidants are being identified as anticarcinogens. Characterizing and optimizing such defense systems may be an important part of a strategy of minimizing cancer and other age-related diseases.

Comparison of data from different countries reveals wide differences in the rates of many types of cancer. This leads to hope that each major type of cancer may be largely avoidable, as is the case for cancers due to tobacco, which constitute 30 percent of the cancer deaths in the United States and the United Kingdom (*1*). Despite numerous suggestions to the contrary, there is no convincing evidence of any generalized increase in U.S. (or U.K.) cancer rates other than what could plausibly be ascribed to the delayed effects of previous increases in tobacco usage (*1–3*). Thus, whether or not any recent changes in life-style or pollution in industrialized countries will substantially affect future cancer risks, some important determinants of current risks remain to be discovered among long-established aspects of our way of life. Epidemiologic studies have indicated that dietary practices are the most promising area to explore (*1, 4*). These studies suggest that a general increase in consumption of fiber-rich cereals, vegetables, and fruits and decrease in consumption of fat-rich products and excessive alcohol would be prudent (*1, 4*). There is still a lack of definitive evidence about the dietary components that are critical for humans and about their mechanisms of action. Laboratory studies of natural foodstuffs and cooked food are beginning to uncover an extraordinary variety of mutagens and possible carcinogens and anticarcinogens. In this article I discuss dietary mutagens and carcinogens and anticarcinogens that seem of importance and speculate on relevant biochemical mechanisms, particularly the role of oxygen radicals and their inhibitors in the fat-cancer relationship, promotion, anticarcinogenesis, and aging.

Natural Mutagens and Carcinogens in Food

Plant material. Plants in nature synthesize toxic chemicals in large amounts, apparently as a primary defense against the hordes of bacterial, fungal, and insect and other animal predators (*5–40*). Plants in the human diet are no exception. The variety of these toxic chemicals is so great that organic chemists have been characterizing them for over 100 years, and new plant chemicals are still being discovered (*12, 24, 25*). However, toxicological studies have been completed for only a very small percentage of them. Recent widespread use of short-term tests for detecting mutagens (*41, 42*) and the increased number of animal cancer tests on plant substances (*6*) have contributed to the identification of many natural mutagens, teratogens, and carcinogens in the human diet (*5–40*). Sixteen examples are discussed below.

1) *Safrole, estragole, methyleugenol*, and related compounds are present in many edible plants (*5*). Safrole, estragole, and methyleugenol are carcinogens in rodents, and several of their metabolites are mutagens (*5*). Oil of sassafras, which had been used in "natural" sarsaparilla root beer, is about 75 percent safrole. Black pepper contains small a[illegible] of safrole and large amounts (close to 10 percent by weight) of the closely related compound *piperine* (*26*). Extracts of black pepper cause tumors in mice at a variety of sites at a dose of extract equivalent to 4 mg of dried pepper per day (about 160 mg/kg per day) for 3 months; an estimate of the average human intake of black pepper is over 140 mg per day (about 2 mg/kg per day) for life (*26*).

2) Most *hydrazines* that have been tested are carcinogens and mutagens, and large amounts of carcinogenic hydrazines are present in edible mushrooms. The widely eaten false morel (*Gyromitra esculenta*) contains 11 hydrazines, three of which are known carcinogens (*28*). One of these, *N*-methyl-*N*-formylhydrazine, is present at a concentration of 50 mg per 100 g and causes lung tumors in mice at the extremely low dietary level of 20 μg per mouse per day (*28*). The most common commercial mushroom, *Agaricus bisporus*, contains about 300 mg of *agaritine*, the δ-glutamyl derivative of the mutagen 4-hydroxymethylphenylhydrazine, per 100 g of mushrooms, as well as smaller amounts of the closely related carcinogen *N*-acetyl - 4 - hydroxymethylphenylhydrazine (*28*). Some agaritine is metabolized by the mushroom to a diazonium derivative which is a very potent carcinogen (a single dose of 400 ng/g gave 30 percent of mice stomach tumors) and which is also present in the mushroom in smaller amounts (*28*). Many hydrazine carcinogens may act by producing oxygen radicals (*43*).

3) Linear *furocoumarins* such as *psoralen derivatives* are potent light-activated carcinogens and mutagens and are widespread in plants of the Umbelliferae family, such as celery, parsnips, figs, and parsley (for instance, 4 mg per 100 g of parsnip) (*17, 19, 44*). The level in celery (about 100 μg per 100 g) can increase about 100-fold if the celery is stressed or diseased (*19*). Celery pickers and handlers commonly develop skin

---

The author is chairman of the Department of Biochemistry, University of California, Berkeley 94720

rashes on their arms when exposed to diseased celery (*19*). Oil of bergamot, a citrus oil, is very rich in a psoralen and was used in the leading suntan lotion in France (*17*). Psoralens, when activated by sunlight, damage DNA and induce tanning more rapidly than the ultraviolet component of sunlight, which is also a carcinogen (*17*). Psoralens (plus light) are also effective in producing oxygen radicals (*18*).

4) The potato glycoalkaloids *solanine* and *chaconine* are strong cholinesterase inhibitors and possible teratogens and are present at about 15 mg per 200 g of potato (*12, 13*). When potatoes are diseased, bruised, or exposed to light, these and other (*24*) glycoalkaloids reach levels that can be lethal to humans (*12*). Plants typically respond to damage by making more (and often different) toxic chemicals as a defense against insects and fungi (*19, 24, 25*). The different cultivars of potatoes vary in the concentration of these toxic glycoalkaloids (the concentration is a major determinant of insect and disease resistance), one cultivar bred for insect resistance had to be withdrawn from use because of its toxicity to humans (> 40 mg of glycoalkaloids in a 200-g potato is considered to be a toxic level) (*12*).

5) *Quercetin* and several similar flavonoids are mutagens in a number of short-term test systems. Flavonoids are extremely widespread (daily levels close to 1 g) in the human diet (*8, 16, 20, 21*). There is evidence for the carcinogenicity of quercetin in two strains of rats (*8*), although it was negative in other experiments (*21*).

6) *Quinones* and their phenol precursors (*9, 14, 16, 23, 45*) are widespread in the human diet. Quinones are quite toxic as they can act as electrophiles or accept a single electron to yield the semiquinone radical, which can either react directly with DNA (*14, 46*) or participate in a redox cycle of superoxide radical generation by transferring the electron to O_2 (*47*). The superoxide radical and its metabolic product H_2O_2 can, in turn, lead to the oxidation of fat in cellular membranes by a lipid peroxidation chain reaction, thus generating mutagens and carcinogens, as discussed below. A number of quinones and dietary phenols have been shown to be mutagens (*7, 9, 16, 23, 44*). Mutagenic anthraquinone derivatives are found in plants such as rhubarb and in mold toxins (*7, 16, 48*). Many dietary phenols can spontaneously autoxidize to quinones, generating hydrogen peroxide at the same time [examples are catechol derivatives such as the caffeic acid component of chlorogenic acid (*9*), which is present at about 250 mg per cup of coffee]. The amounts of these phenols in human urine (and in the diet) are appreciable (*45*). Catechol, for example, is excreted in urine at about 10 mg per day and appears to be mainly derived from metabolism of plant substances (*45*). Catechol is a potent promoter of carcinogenesis (*45*), an inducer of DNA damage, a likely active metabolite of the carcinogen benzene (*46*), and a toxic agent in cigarette smoke (*45*). Catecholamine induction of cardiomyopathy is thought to occur through generation of oxygen radicals (*49*).

7) *Theobromine*, a relative of caffeine, has been shown to be genotoxic in a variety of tests, to potentiate (as does caffeine) DNA damage by various carcinogens in human cells, and to cause testicular atrophy and spermatogenic cell abnormalities in rats (*27*). Cocoa powder is about 2 percent theobromine, and therefore humans may consume hundreds of milligrams of theobromine a day from chocolate. Theobromine is also present in tea.

8) *Pyrrolizidine* alkaloids are carcinogenic, mutagenic, and teratogenic and are present in thousands of plant species (often at > 1 percent by weight), some of which are ingested by humans, particularly in herbs and herbal teas and occasionally in honey (*7, 29*). Pyrrolizidine alkaloid poisonings in humans (as well as in other mammals) cause lung and liver lesions and are commonly misdiagnosed (*29*).

9) The broad (fava) bean (*Viria faba*), a common food of the Mediterranean region, contains the toxins *vicine* and *convicine* at a level of about 2 percent of the dry weight (*30*). Pythagoras forbade his followers to eat the beans, presumably because he was one of the millions of Mediterranean people with a deficiency of glucose-6-phosphate dehydrogenase. This deficiency results in a low glutathione concentration in blood cells, which causes increased resistance to the malarial parasite, probably accounting for the widespread occurrence of the mutant gene in malarial regions. However, the low glutathione concentration also results in a marked sensitivity to agents that cause oxidative damage, such as the fava bean toxins and a variety of drugs and viruses. Sensitive individuals who ingest fava beans develop a severe hemolytic anemia caused by the enzymatic hydrolysis of vicine to its aglycone, *divicine*, which forms a quinone that generates oxygen radicals (*30*).

10) *Allyl isothiocyanate*, a major flavor ingredient in oil of mustard and horseradish, is one of the main toxins of the mustard seed and has been shown to cause chromosome aberrations in hamster cells at low concentration (*50*) and to be a carcinogen in rats (*31*).

11) *Gossypol* is a major toxin in cottonseed and accounts for about 1 percent of its dry weight (*32*). Gossypol causes pathological changes in rat and human testes, abnormal sperm, and male sterility (*32, 33*). Genetic damage has been observed in embryos sired by gossypol-treated male rats: dominant lethal mutations in embryos were measured after males were taken off gossypol treatment and allowed to mate (*33*). Gossypol appears to be a carcinogen as well: it has been reported to be a potent initiator and also a promoter of carcinogenesis in skin painting studies with mice (*34*). Crude, unrefined cottonseed oil contains considerable amounts of gossypol (100 to 750 mg per 100 ml). Thus human consumption may be appreciable in countries, such as Egypt, where fairly crude cottonseed oil is commonly used in cooking. Gossypol is being tested as a male contraceptive in over 10,000 people in China (at an oral dose of about 10 mg per person per day), as it is inexpensive and causes sterility during use (*33*). Gossypol's mode of action as a spermicide may be through the production of oxygen radicals (*35*).

Plant breeders have developed "glandless cotton," a new strain with low levels of gossypol, but seeds from this strain are much more susceptible to attack by the fungus *Aspergillus flavus*, which produces the potent carcinogen aflatoxin (*36*).

12) *Sterculic acid* and *malvalic acid* are widespread in the human diet. They are toxic cyclopropenoid fatty acids present in cottonseed oil and other oils from seeds of plants in the family Malvaceal (for instance, cotton, kapok, okra, and durian) (*51*). Another possible source of human exposure is consumption of fish, poultry, eggs, and milk from animals fed on cottonseed (*51*). Cyclopropenoid fatty acids are carcinogens in trout, markedly potentiate the carcinogenicity of aflatoxin in trout, cause atherosclerosis in rabbits, are mitogenic in rats, and have a variety of toxic effects in farm animals (*51*). The toxicity of these fatty acids could be due to their ease of oxidation to form peroxides and radicals (*51*).

13) Leguminous plants such as lupine contain very potent teratogens (*22*). When cows and goats forage on these plants, their offspring may have severe teratogenic abnormalities; an example is

the characteristic "crooked calf" abnormality due to the ingestion of *anagyrine* from lupine (*22*). In addition, significant amounts of these teratogens are transferred to the animals' milk, so that drinking the milk during pregnancy is a serious teratogenic hazard (*22*). In one rural California family, a baby boy, a litter of puppies, and goat kids all had "crooked" bone birth-defect abnormalities. The pregnant mother and the dog had both been drinking milk obtained from the family goats, which had been foraging on lupine (the main forage in winter) (*22*). It was at first mistakenly thought that the birth defects were caused by spraying of 2,4-D.

14) *Sesquiterpene lactones* are widespread in many plants (*37*), although because they are bitter they are not eaten in large amounts. Some have been shown to be mutagenic (*37*). They are a major toxin in the white sap of *Lactuca virosa* (poison lettuce), which has been used as a folk remedy. Plant breeders are now transferring genes from this species to commercial lettuce to increase insect resistance (*38*).

15) The *phorbol esters* present in the Euphorbiacea, some of which are used as folk remedies or herb teas, are potent promoters of carcinogenesis and may have been a cause of nasopharyngeal cancer in China and esophageal cancer in Curaçao (*39*).

16) Alfalfa sprouts contain *canavanine*, a highly toxic arginine analog that is incorporated into protein in place of arginine. Canavanine, which occurs in alfalfa sprouts at about 1.5 percent of their dry weight (*40*), appears to be the active agent in causing the severe lupus erythematosus–like syndrome seen when monkeys are fed alfalfa sprouts (*40*). Lupus in man is characterized by a defect in the immune system which is associated with autoimmunity, antinuclear antibodies, chromosome breaks, and various types of pathology (*40*). The chromosome breaks appear to be due to oxygen radicals as they are prevented by superoxide dismutase (*52*). The canavanine–alfalfa sprout pathology could be due in part to the production of oxygen radicals during phagocytization of antibody complexes with canavanine-containing protein.

The 16 examples above, plus coffee (discussed below), illustrate that the human dietary intake of "nature's pesticides" is likely to be several grams per day—probably at least 10,000 times higher than the dietary intake of man-made pesticides (*53*).

Levels of plant toxins that confer insect and fungal resistance are being increased or decreased by plant breeders (*38*). There are health costs for the use of these natural pesticides, just as there are for man-made pesticides (*41*, *54*), and these must be balanced against the costs of producing food. However, little information is available about the toxicology of most of the natural plant toxins in our diet, despite the large doses we are exposed to. Many, if not most, of these plant toxins may be "new" to humans in the sense that the human diet has changed drastically with historic times. By comparison, our knowledge of the toxicological effects of new man-made pesticides is extensive, and general exposure is exceedingly low (*53*).

Plants also contain a variety of anticarcinogens (*55*), which are discussed below.

Alcohol. Alcohol has long been associated with cancer of the mouth, esophagus, pharynx, larynx, and, to a lesser extent, liver (*1*, *56*), and it appears to be an important human teratogen, causing a variety of physical and mental defects in babies of mothers who drink (*57*). Alcohol drinking causes sperm abnormalities in mice (*57a*) and is a synergist for chromosome damage in humans (*58*). Alcohol metabolism generates acetaldehyde, which is a mutagen and teratogen (*59*), a cocarcinogen, and possibly a carcinogen (*60*), and also radicals that produce lipid hydroperoxides (*61*) and other mutagens and carcinogens (*62*, see below). In some epidemiologic studies on alcohol (*56*), it has been suggested that dietary green vegetables are a modifying factor in the reduction of cancer risk.

Mold carcinogens. A variety of mold carcinogens and mutagens are present in mold-contaminated food such as corn, grain, nuts, peanut butter, bread, cheese, fruit, and apple juice (*15*, *63*). Some of these, such as sterigmatocystin and aflatoxin, are among the most potent carcinogens and mutagens known (*15*, *63*). Dietary glutathione has been reported to counteract aflatoxin carcinogenicity.

Nitrite, nitrate, and nitrosamines. A number of human cancers, such as stomach and esophageal cancer, may be related to nitrosamines and other nitroso compounds formed from nitrate and nitrite in the diet (*64*, *65*). Beets, celery, lettuce, spinach, radishes, and rhubarb all contain about 200 mg of nitrate per 100-g portion (*65*). Anticarcinogens in the diet may be important in this context as well (*66*).

Fat and cancer: possible oxidative mechanisms. Epidemiologic studies of cancer in humans suggest, but do not prove, that high fat intake is associated with colon and breast cancer (*1*, *4*, *67*). A number of animal studies have shown that high dietary fat is a promoter and a presumptive carcinogen (*4*, *67*, *68*). Colon and breast cancer and lung cancer (which is almost entirely due to cigarette smoking) account for about half of all U.S. cancer deaths. In addition to the cyclopropenoid fatty acids already discussed, two other plausible mechanisms involving oxidative processes could account for the relation (*69*) between high fat and both cancer and heart disease.

1) *Rancid fat*. Fat accounts for over 40 percent of the calories in the U.S. diet (*67*), and the amount of ingested oxidized fat may be appreciable (*70*, *71*). Unsaturated fatty acids and cholesterol in fat are easily oxidized, particularly during cooking (*70*, *71*). The lipid peroxidation chain reaction (rancidity) yields a variety (*71–73*) of mutagens, promoters, and carcinogens such as fatty acid hydroperoxides (*62*), cholesterol hydroperoxide (*74*), endoperoxides, cholesterol and fatty acid epoxides (*74–77*), enals and other aldehydes (*44*, *59*, *78*), and alkoxy and hydroperoxy radicals (*44*, *72*). Thus the colon and digestive tract are exposed to a variety of fat-derived carcinogens. Human breast fluid can contain enormous levels (up to 780 μ*M*) (*75*) of cholesterol epoxide (an oxidation product of cholesterol), which could originate from either ingested oxidized fat or oxidative processes in body lipids. Rodent feeding studies with oxidized fat (*79*) have not yielded definitive results.

2) *Peroxisomes* oxidize an appreciable percentage of dietary fatty acids, and removal of each two-carbon unit generates one molecule of hydrogen peroxide (a mutagen, promoter, and carcinogen) (*80*, *81*). Some hydrogen peroxide escapes the catalase in the peroxisome (*80*, *82*, *83*), thus contributing to the supply of oxygen radicals, which also come from other metabolic sources (*72*, *83–85*). Hydroperoxides generate oxygen radicals in the presence of iron-containing compounds in the cell (*72*). Oxygen radicals, in turn, can damage DNA and can start the rancidity chain reaction which leads to the production of the mutagens and carcinogens listed above (*72*). Drugs such as clofibrate, which cause lowering of serum lipids and proliferation of peroxisomes in rodents, result in age pigment (lipofuscin) accumulation (a sign of lipid peroxidation in tissues) and liver tumors in animals (*80*). Some fatty acids, such as $C_{22:1}$ and certain *trans* fatty acids, appear to cause peroxisomal proliferation because they are poorly oxidized in mitochondria and are preferentially oxidized in the peroxisomes, although they may be selective for heart or

liver (*86*). There has been controversy about the role of *trans* fatty acids in cancer and heart disease, and recent evidence suggests that *trans* fatty acids might not be a risk factor for atherosclerosis in experimental animals (*87*). Americans consume about 12 g of *trans* fatty acids a day (*87*) and a similar amount of unnatural *cis* isomers [which need further study (*88*)], mainly from hydrogenated vegetable fats. Dietary $C_{22:1}$ fatty acids are also obtained from rapeseed oil and fish oils (*86*). Thus oxidation of certain fatty acids might generate grams of hydrogen peroxide per day within the peroxisome (*86*). Another source of fat toxicity could be perturbations in the mitochondrial or peroxisomal membranes caused by abnormal fatty acids, yielding an increased flux of superoxide and hydrogen peroxide. Mitochondrial structure is altered when rats are fed some abnormal fatty acids from partially hydrogenated fish oil (*89*). Dietary $C_{22:1}$ fatty acids and clofibrate also induce ornithine decarboxylase (*86*), a common attribute of promoters.

A recent National Academy of Sciences committee report suggests that a reduction of fat consumption in the American diet would be prudent (*4*), although other scientists argue that, until we know more about the mechanism of the fat-cancer relation and about which types of fat are dangerous, it is premature to recommend dietary changes (*90*).

Cooked Food as a Source of Ingested Burnt and Browned Material

Work of Sugimura and others has indicated that the burnt and browned material from heating protein during cooking is highly mutagenic (*21, 91*). Several chemicals isolated on the basis of their mutagenicity from heated protein or pyrolyzed amino acids were found to be carcinogenic when fed to rodents (*21*). In addition, the browning reaction products from the caramelization of sugars or the reaction of amino acids and sugars during cooking (for instance, the brown material on bread crusts and toasted bread) contain a large variety of DNA-damaging agents and presumptive carcinogens (*23, 38, 92*). The amount of burnt and browned material in the human diet may be several grams per day. By comparison about 500 mg of burnt material is inhaled each day by a smoker using two packs of cigarettes (at 20 mg of tar per cigarette) a day. Smokers have more easily detectable levels of mutagens in their urine than nonsmokers (*93*), but so do people who have consumed a meal of fried pork or bacon (*94*). In the evaluation of risk from burnt material it may be useful (in addition to carrying out epidemiologic studies) to compare the activity of cigarette tar to that of the burnt material from cooked food (or polluted air) in short-term tests and animal carcinogenicity tests involving relevant routes of exposure. Route of exposure and composition of the burnt material are critical variables. The risk from inhaled cigarette smoke can be one reference standard: an average life shortening of about 8 years for a two-pack-a-day smoker. The amount of burnt material inhaled from severely polluted city air, on the other hand, is relatively small: it would be necessary to breathe smoggy Los Angeles air (111 μg/m^3 total particulates, 31 μg/m^3 soluble organic matter) for 1 to 2 weeks to equal the soluble organic matter of the particulates or the mutagenicity from one cigarette (20 mg of tar) (*95*). Epidemiologic studies have not shown significant risks from city air pollution alone (*1, 96*). Air in the houses of smokers is considerably more polluted than city air outside (*97*).

Coffee, which contains a considerable amount of burnt material, including the mutagenic pyrolysis product methylglyoxal, is mutagenic (*21, 98*). However, one cup of coffee also contains about 250 mg of the natural mutagen chlorogenic acid (*9*) [which is also an antinitrosating agent (*66*)], highly toxic atractylosides (*10*), the glutathione transferase inducers kahweal palmitate and cafestol palmitate (*11*), and about 100 mg of caffeine [which inhibits a DNA-repair system and can increase tumor yield (*99*) and cause birth defects at high levels in several experimental species (*100*)]. There is preliminary, but not conclusive, epidemiologic evidence that heavy coffee drinking is associated with cancer of the ovary, bladder, pancreas, and large bowel (*101*).

Cooking also accelerates the rancidity reaction of cooking oils and fat in meat (*70, 71*), thus increasing consumption of mutagens and carcinogens.

Anticarcinogens

We have many defense mechanisms to protect ourselves against mutagens and carcinogens, including continuous shedding of the surface layer of our skin, stomach, cornea, intestines, and colon (*102*). Understanding these mechanisms should be a major goal of cancer, heart, and aging research. Among the most important defenses may be those against oxygen radicals and lipid peroxidation if, as discussed here, these agents are major [illegible]itors to DNA damage (*103*). Major sources of endogenous oxygen radicals are hydrogen peroxide (*83*) and superoxide (*72, 104*) generated as side products of metabolism, and the oxygen radical burst from phagocytosis after viral or bacterial infection or the inflammatory reaction (*105*). A variety of environmental agents could also contribute to the oxygen radical load, as discussed here and in recent reviews (*72, 106*). Many enzymes protect cells from oxidative damage: examples are superoxide dismutase (*104*), glutathione peroxidase (*107*), DT-diaphorase (*108*), and the glutathione transferases (*109*). In addition, a variety of small molecules in our diet are required for antioxidative mechanisms and appear to be anticarcinogens; some of these are discussed below.

1) *Vitamin E* (tocopherol) is the major radical trap in lipid membranes (*72*) and has been used clinically in a variety of oxidation-related diseases (*110*). Vitamin E ameliorates both the cardiac damage and carcinogenicity of the quinones adriamycin and daunomycin, which are mutagenic, carcinogenic, cause cardiac damage, and appear to be toxic because of free radical generation (*111*). Protective effects of tocopherols against radiation-induced DNA damage and mutation and dimethylhydrazine-induced carcinogenesis have also been observed (*112*). Vitamin E markedly increases the endurance of rats during heavy exercise, which causes extensive oxygen radical damage to tissues (*113*).

2) β-*Carotene* is another antioxidant in the diet that could be important in protecting body fat and lipid membranes against oxidation. Carotenoids are free-radical traps and remarkably efficient quenchers of singlet oxygen (*114*). Singlet oxygen is a very reactive form of oxygen which is mutagenic and particularly effective at causing lipid peroxidation (*114*). It can be generated by pigment-mediated transfer of the energy of light to oxygen, or by lipid peroxidation, although the latter is somewhat controversial. β-Carotene and similar polyprenes are present in carrots and in all food that contains chlorophyll, and they appear to be the plants' main defense against singlet oxygen generated as a by-product from the interaction of light and chlorophyll (*115*). Carotenoids have been shown to be anticarcinogens in rats and mice (*116*). Carotenoids (in green and yellow vegetables) may be anticarcinogens in humans (*1, 56, 117*). Their protective effects in smokers might be related to the high level of oxidants in both cigarette smoke and tar (*45, 118*). Carotenoids have been used medically in

the treatment for some genetic diseases, such as porphyrias, where a marked photosensitivity is presumably due to singlet oxygen formation (*119*).

3) *Selenium* is another important dietary anticarcinogen. Dietary selenium (usually selenite) significantly inhibits the induction of skin, liver, colon, and mammary tumors in experimental animals by a number of different carcinogens, as well as the induction of mammary tumors by viruses (*120*). It also inhibits transformation of mouse mammary cells (*121*). Low selenium concentrations may be a risk factor in human cancer (*122*). A particular type of heart disease in young people in the Keshan area of China has been traced to a selenium deficiency, and low selenium has been associated with cardiovascular death in Finland (*123*). Selenium is in the active site of glutathione peroxidase, an enzyme essential for destroying lipid hydroperoxides and endogenous hydrogen peroxide and thus helping to prevent oxygen radical–induced lipid peroxidation (*107*), although not all of the effects of selenium may be accounted for by this enzyme (*120*). Several heavy-metal toxins, such as Cd^{2+} (a known carcinogen) and Hg^{2+}, lower glutathione peroxidase activity by interacting with selenium (*107*). Selenite (and vitamin E) has been shown to counter the oxidative toxicity of mercuric salts (*124*).

4) *Glutathione* is present in food and is one of the major antioxidants and antimutagens in the soluble fraction of cells. The glutathione transferases (some of which have peroxidase activity) are major defenses against oxidative and alkylating carcinogens (*109*). The concentration of glutathione may be influenced by dietary sulfur amino acids (*125*, *126*). *N*-Acetylcysteine, a source of cysteine, raises glutathione concentrations and reduces the oxidative cardiotoxicity of adriamycin and the skin reaction to radiation (*127*). Glutathione concentrations are raised even more efficiently by L-2-oxothiazolidine-4-carboxylate, which is an effective antagonist of acetaminophen-caused liver damage (*126*). Acetaminophen is thought to be toxic through radical and quinone oxidizing metabolites (*128*). Dietary glutathione may be an effective anticarcinogen against aflatoxin (*129*).

5) Dietary *ascorbic acid* is also important as an antioxidant. It was shown to be anticarcinogenic in rodents treated with ultraviolet radiation, benzo[*a*]pyrene, and nitrite (forming nitroso carcinogens) (*64*, *65*, *130*), and it may be inversely associated with human uterine cervical dysplasia (although this is not proof of a cause-effect relationship) (*131*). It was recently hypothesized that ascorbic acid may have been supplemented and perhaps partially replaced in humans by uric acid during primate evolution (*132*).

6) *Uric acid* is a strong antioxidant present in high concentrations in the blood of humans (*132*). The concentration of uric acid in the blood can be increased by dietary purines; however, too much causes gout. Uric acid is also present in high concentrations in human saliva (*132*) and may play a role in defense there as well, in conjunction with lactoperoxidase. A low uric acid level in blood may possibly be a risk factor in cigarette-caused lung cancer in humans (*133*).

7) Edible plants and a variety of substances in them, such as phenols, have been reported to inhibit (cabbage) or to enhance (beets) carcinogenesis (*11*, *55*, *134*) or mutagenesis (*23*, *66*, *92*, *135*) in experimental animals. Some of these substances appear to inhibit by inducing cytochrome P-450 and other metabolic enzymes [(*134*); see also (*11*)], although on balance it is not completely clear whether it is generally helpful or harmful for humans to ingest these inducing substances.

The hypothesis that as much as 80 percent of cancer could be due to environmental factors was based on geographic differences in cancer rates and studies of migrants (*136*). These differences in cancer rates were thought to be mainly due to life-style factors, such as smoking and dietary carcinogens and promoters (*136*), but they also may be due in good part [see also (*1*)] to less than optimum amounts of anticarcinogens and protective factors in the diet.

The optimum levels of dietary antioxidants, which may vary among individuals, remain to be determined; however, at least for selenium (*120*), it is important to emphasize the possibility of deleterious side effects at high doses.

Oxygen Radicals and Degenerative Diseases Associated with Aging

Aging. A plausible theory of aging holds that the major cause is damage to DNA (*102*, *137*) and other macromolecules and that a major source of this damage is oxygen radicals and lipid peroxidation (*43*, *84*, *103*, *138–141*). Cancer and other degenerative diseases, such as heart disease (*102*), are likely to be due in good part to this same fundamental destructive process. Age pigment (lipofuscin) accumulates during aging in all mammalian species and has been associated with lipid peroxidation (*73*, *84*, *138*, *139*). The fluorescent products in age pigment are thought to be formed by malondialdehyde (a mutagen and carcinogen and a major end product of rancidity) cross-linking protein and lipids (*138*). Metabolic rate is directly correlated with the rate of lipofuscin formation (and inversely correlated with longevity) (*139*).

Cancer increases with about the fourth power of age, both in short-lived species such as rats and mice (about 30 percent of rodents have cancer by the end of their 2- to 3-year life-span) and in long-lived species such as humans (about 30 percent of people have cancer by the end of their 85-year life-span) (*142*). Thus, the marked increase in life-span that has occurred in 60 million years of primate evolution has been accompanied by a marked decrease in age-specific cancer rates; that is, in contrast to rodents, 30 percent of humans do not have cancer by the age of 3 (*142*). One important factor in longevity appears to be basal metabolic rate (*139*, *141*), which is much lower in man than in rodents and could markedly affect the level of endogenous oxygen radicals.

Animals have many antioxidant defenses against oxygen radicals. Increased levels of these antioxidants, as well as new antioxidants, may also be a factor in the evolution of man from short-lived prosimians (*143*). It has been suggested that an increase in superoxide dismutase is correlated (after the basal metabolic rate is taken into account) with increased longevity during primate evolution, although this has been disputed (*141*). Ames *et al.* proposed (*132*) that as uric acid was an antioxidant and was present in much higher concentrations in the blood of humans than in other mammals, it may have been one of the innovations enabling the marked increase in life span and consequent marked decrease in age-specific cancer rates which occurred during primate evolution. The ability to synthesize ascorbic acid may have been lost at about the same time in primate evolution as uric acid levels began to increase (*144*).

Cancer and promotion. Both DNA-damaging agents (initiating mutagens) (*21*, *41*, *42*) and promoters (*145*) appear to play an important role in carcinogenesis (*21*, *146*). It has been postulated that certain promoters of carcinogenesis act by generation of oxygen radicals and resultant lipid peroxidation (*73*, *146–149*). Lipid peroxidation cross-links proteins (*43*, *150*) and affects all aspects of cell organization (*72*), including membrane and surface structure, and the mitotic apparatus. A common property of promoters may be their ability to produce oxygen radicals. Some examples are fat and hydrogen peroxide (which may be among the most important promoters) (*67, 68, 81*), TCDD (*151*), lead and cadmium (*152*), phorbol esters (*147, 149, 153*), wounding of tissues (*154*), asbestos (*155*), peroxides (*156*), catechol (*45*) (see quinones above), mezerein and teleocidin B (*147*), phenobarbital (*157*), and radiation (*72, 158*). Inflammatory reactions involve the production of oxygen radicals by phagocytes (*105*), and this could be the basis of promotion for asbestos (*155*) or wounding (*154*). Some of the antioxidant anticarcinogens (discussed above) are also antipromoters (*73, 121, 146, 159, 160*), and phorbol ester–induced chromosome damage (*149*) or promotion of transformation (*159*) is suppressed by superoxide dismutase, as would be expected if promoters were working through oxidative mechanisms. Many "complete" carcinogens cause the production of oxygen radicals (*73, 161*); examples are nitroso compounds, hydrazines, quinones, polycyclic hydrocarbons (through quinones), cadmium and lead salts, nitro compounds, and radiation. A good part of the toxic effects of ionizing radiation damage to DNA and cells is thought to be due to generation of oxygen radicals (*103, 162*), although only a tiny part of the oxygen radical load in humans is likely to be from this source.

Recent studies give some clues as to how promoters might act. Promoters disrupt the mitotic apparatus, causing hemizygosity and expression of recessive genes (*163*). Phorbol esters generate oxygen radicals, which cause chromosome breaks (*164*) and increase gene copy number (*165*). Promoters also cause formation of the peroxide hormones of the prostaglandin and leukotriene family by oxidation of arachidonic acid and other C_{20} polyenoic fatty acids, and inhibitors of this process appear to be antipromoters (*160*). These hormones are intimately involved in cell division, differentiation, and tumor growth (*166*) and could have arisen in evolution as signal molecules warning the cell of oxidative damage. Effects on the cell membrane have also been suggested as the important factor in promotion, causing inhibition of intercellular communication (*167*) or protein kinase activation (*167a*).

Heart disease. It has been postulated that atherosclerotic lesions, which are derived from single cells, are similar to benign tumors and are of somatic mutational origin (*102, 168*). Fat appears to be one major risk factor for heart disease as well as for colon and breast cancer (*69*). In agreement with this, a strong correlation has been observed between the frequency of atherosclerotic lesions and adenomatous polyps of the colon (*69*). Thus, the same oxidative processes involving fat may contribute to both diseases. Oxidized forms of cholesterol have been implicated in heart disease (*169*), and atherosclerotic-like lesions have been produced by injecting rabbits with lipid hydroperoxide or oxidized cholesterol (*169*). The anticarcinogens discussed above could be anti–heart disease agents as well. As pointed out in the preceding section, vitamin E ameliorates both the cardiac damage and carcinogenicity of the free-radical-generating quinones adriamycin and daunomycin; *N*-acetylcysteine reduces the cardiotoxicity of adriamycin; and selenium is an antirisk factor for one type of heart disease.

Other diseases. The brain uses 20 percent of the oxygen consumed by man and contains an appreciable amount of unsaturated fat. Lipid peroxidation (with consequent age pigment) is known to occur readily in the brain (*72*), and possible consequences could be senile dementia or other brain abnormalities (*84*). Several inherited progressive diseases of the central nervous system, such as Batten's disease, are associated with lipofuscin accumulation and may be due to a lipid peroxidation caused by a high concentration of unbound iron (*170*). Mental retardation is one consequence of an inherited defective DNA repair system (XP complementation group D) for depurinated sites in DNA (*171*).

Senile cataracts have been associated with light-induced oxidative damage (*172*). The retina and an associated layer of cells, the pigment epithelium, are extremely sensitive to degeneration in vitamin E and selenium deficiency (*173*). The pigment epithelium accumulates massive amounts of lipofuscin in aging and dietary antioxidant deficiency (*173*). The eye is well known to be particularly rich in antioxidants.

The testes are quite prone to lipid peroxidation and to the accumulation of age pigment. A number of agents, such as gossypol, which cause genetic birth defects (dominant lethals) may be active by this mechanism. The various agents known to cause cancer by oxidative mechanisms are prospective mutagenic agents for the germ line. Thus, vitamin E, which was discovered 60 years ago as a fertility factor (*72*), and other antioxidants such as selenium (*174*), may help both to engender and to protect the next generation.

Risks

There are large numbers of mutagens and carcinogens in every meal, all perfectly natural and traditional [see also (*21, 23*)]. Nature is not benign. It should be emphasized that no human diet can be entirely free of mutagens and carcinogens and that the foods mentioned are only representative examples. To identify a substance, whether natural or man-made, as a mutagen or a carcinogen, is just a first step. Beyond this, it is necessary to consider the risks for alternative courses of action and to quantitate the approximate magnitude of the risk, although the quantification of risk poses a major challenge. Carcinogens differ in their potency in rodents by more than a millionfold (*175*), and the levels of particular carcinogens to which humans are exposed can vary more than a billionfold. Extrapolation of risk from rodents to humans is difficult for many reasons, including the longevity difference, antioxidant factors, and the probable multicausal nature of most human cancer.

Tobacco smoking is, without doubt, a major and well-understood risk, causing about 30 percent of cancer deaths and 25 percent of fatal heart attacks (as well as other degenerative diseases) in the United States (*1*). These percentages may increase even more in the near future as the health effects of the large increase in women smokers become apparent (*1*). Diet, which provides both carcinogens and anticarcinogens, is extremely likely to be another major risk factor. Excessive alcohol consumption is another risk, although it does not seem to be of the same general importance as smoking and diet. Certain other high-dose exposures might also turn out to be important for particular groups of people—for instance, certain drugs, where consumption can reach hundreds of milligrams per day; particular cosmetics; and certain occupational exposures (*2*), where workers inhale dusts or solvents at high concentration. We must also be prudent about environmental pollution (*41, 54*). Despite all of these risks, it should be emphasized that the overall trend in life expectancy in the United States is continuing steadily upward (*176*).

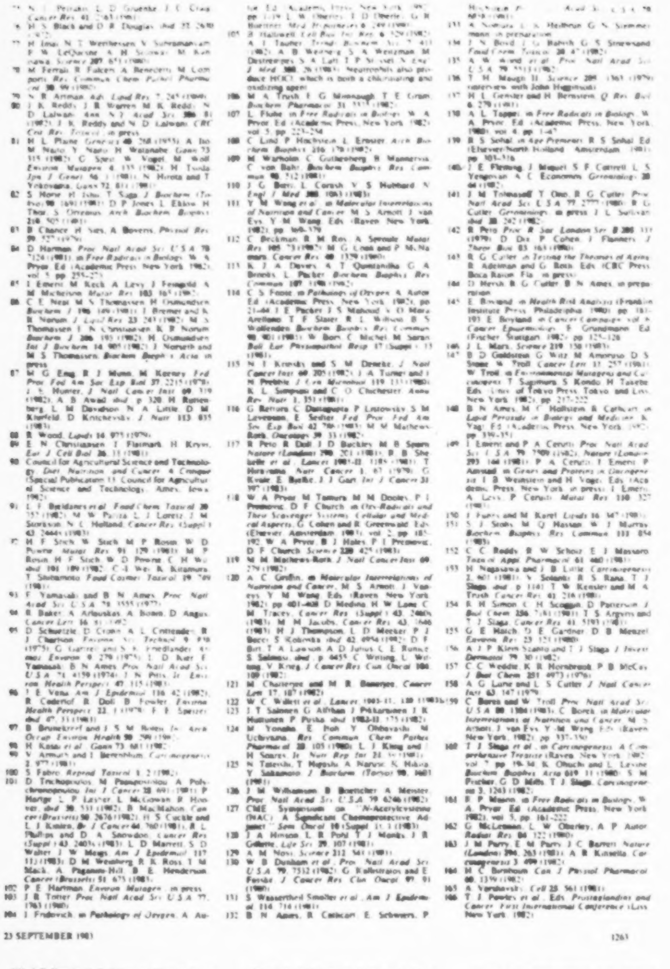
The understanding of cancer and degenerative disease mechanisms is being aided by the rapid progress of science and technology, and this should help to dispel confusion about how important health risks can be identified among the vast number of minor risks. We have many methods of attacking the problem of environmental carcinogens (and anticarcinogens), including human epidemiology (*1*), short-term tests (*41*, *42*, *177*), and animal cancer tests (*175*). Powerful new methods are being developed [for instance, see (*58*, *177*)] for measuring DNA damage or other pertinent factors with great sensitivity in individuals. These methods, which are often noninvasive as they can be done on blood or urine (even after storage), can be combined with epidemiology to determine whether particular factors are predictive of disease. Thus, more powerful tools will be available for optimizing antioxidants and other dietary anti-risk factors, for identifying human genetic variants at high risk, and for identifying significant health risks.

References and Notes

1. R. Doll and R. Peto, *J. Natl. Cancer Inst.* **66**, 1192 (1981).
2. R. Peto and M. Schneiderman, Eds., *Banbury Report 9. Quantification of Occupational Cancer* (Cold Spring Harbor Laboratory, Cold Spring Harbor, N.Y., 1981).
3. *Cancer Facts and Figures, 1983* (American Cancer Society, New York, 1982).
4. National Research Council, *Diet, Nutrition and Cancer* (National Academy Press, Washington, D.C., 1982).
5. E. C. Miller, J. A. Miller, I. Hirono, T. Sugimura, S. Takayama, Eds., *Naturally Occurring Carcinogens-Mutagens and Modulators of Carcinogenesis* (Japan Scientific Societies Press and University Park Press, Tokyo and Baltimore, 1979); E. C. Miller *et al.*, *Cancer Res.* **43**, 1124 (1983); C. Ioannides, M. Delaforge, D. V. Parke, *Food Cosmet. Toxicol.* **19**, 657 (1981).
6. G. J. Kapadia, Ed., *Oncology Overview on Naturally Occuring Dietary Carcinogens of Plant Origin* (International Cancer Research Data Bank Program, National Cancer Institute, Bethesda, Maryland, 1982).
7. A. M. Clark, in *Environmental Mutagenesis, Carcinogenesis, and Plant Biology*, E. J. Klekowski, Jr., Ed. (Praeger, New York, 1982), vol. 1, pp. 97–132.
8. A. M. Pamukcu, S. Yalciner, J. F. Hatcher, G. T. Bryan, *Cancer Res.* **40**, 3468 (1980); J. F. Hatcher, A. M. Pamukcu, E. Erturk, G. T. Bryan, *Fed. Proc. Fed. Am. Soc. Exp. Biol.* **42**, 786 (1983).
9. H. F. Stich, M. P. Rosin, C. H. Wu, W. D. Powrie, *Mutat. Res.* **90**, 201 (1981); A. A. Aver'yanov, *Biokhimiya* **46**, 256 (1981); A. F. Hanham, B. P. Dunn, H. F. Stich, *Mutat. Res.* **116**, 333 (1983).
10. K. H. Pegel, *Chem. Eng. News* **59**, 4 (20 July 1981).
11. L. K. T. Lam, V. L. Sparnins, L. W. Wattenberg, *Cancer Res.* **42**, 1193 (1982).
12. S. J. Jadhav, R. P. Sharma, D. K. Salunkhe, *CRC Crit. Rev. Toxicol.* **9**, 21 (1981).
13. R. L. Hall, *Nutr. Cancer* **1** (No. 2), 27 (1979).
14. H. W. Moore and R. Czerniak, *Med. Res. Rev.* **1**, 249 (1981).
15. I. Hirono, *CRC Crit. Rev. Toxicol.* **8**, 235 (1981).
16. J. P. Brown, *Mutat. Res.* **75**, 243 (1980).
17. M. J. Ashwood-Smith and G. A. Poulton, *ibid.* **85**, 389 (1981).
18. A. Ya. Potapenko, M. V. Moshnin, A. A. Krasnovsky, Jr., V. L. Sukhorukov, *Z. Naturforsch.* **37**, 70 (1982).
19. G. W. Ivie, D. L. Holt, M. C. Ivey, *Science* **213**, 909 (1981); R. C. Beier and E. H. Oertli, *Phytochemistry*, in press; R. C. Beier, G. W. Ivie, E. H. Oertli, in "Xenobiotics in Foods and Feeds," *ACS Symp. Ser.*, in press; ———, D. L. Holt, *Food Chem. Toxicol.* **21**, 163 (1983).
20. G. Tamura, C. Gold, A. Ferro-Luzzi, B. N. Ames, *Proc. Natl. Acad. Sci. U.S.A.* **77**, 4961 (1980).
21. T. Sugimura and S. Sato, *Cancer Res. (Suppl.)* **43**, 2415s (1983); T. Sugimura and M. Nagao, in *Mutagenicity: New Horizons in Genetic Toxicology*, J. A. Heddle, Ed. (Academic Press, New York, 1982), pp. 73–88.
22. W. W. Kilgore, D. G. Crosby, A. L. Craigmill, N. K. Poppen, *Calif. Agric.* **35** (No. 11) (November 1981); D. G. Crosby, *Chem. Eng. News* **61**, 37 (11 April 1983); C. D. Warren, *ibid.*, p. 3 (13 June 1983).
23. H. F. Stich, M. P. Rosin, C. H. Wu, W. D. Powrie, in *Mutagenicity: New Horizons in Genetic Toxicology*, J. A. Heddle, Ed. (Academic Press, New York, 1982), pp. 117–142; ———, W. D. Powrie, *Cancer Lett.* **14**, 251 (1981).
24. N. Katsui, F. Yagihashi, A. Murai, T. Masamune, *Bull. Chem. Soc. Jpn.* **55**, 2424 (1982); ———, *ibid.*, p. 2428; R. M. Bostock, R. A. Laine, J. A. Kuc, *Plant Physiol.* **70**, 1417 (1982).
25. H. Griesebach and J. Ebel, *Angew. Chem. Int. Ed. Engl.* **17**, 635 (1978).
26. J. M. Concon, D. S. Newburg, T. W. Swerczek, *Nutr. Cancer* **1** (No. 3), 22 (1979).
27. H. W. Renner and R. Munzner, *Mutat. Res.* **103**, 275 (1982); H. W. Renner, *Experientia* **38**, 600 (1982); D. Mourelatos, J. Dozi-Vassiliades, A. Granitsas, *Mutat. Res.* **104**, 243 (1982); J. H. Gans, *Toxicol. Appl. Pharmacol.* **63**, 312 (1982).
28. B. Toth, in *Naturally Occurring Carcinogens-Mutagens and Modulators of Carcinogenesis*, E. C. Miller, J. A. Miller, I. Hirono, T. Sugimura, S. Takayama, Eds. (Japan Scientific Societies Press and University Park Press, Tokyo and Baltimore, 1979), pp. 57–65; A. E. Ross, D. L. Nagel, B. Toth, *J. Agric. Food Chem.* **30**, 521 (1982); B. Toth and K. Patil, *Mycopathologia* **78**, 11 (1982); B. Toth, D. Nagel, A. Ross, *Br. J. Cancer* **46**, 417 (1982).
29. R. Schoental, *Toxicol. Lett.* **10**, 323 (1982); R. J. Huxtable, *Perspect. Biol. Med.* **24**, 1 (1980); H. Niwa, H. Ishiwata, K. Yamada, *J. Chromatogr.* **257**, 146 (1983).
30. M. Chevion and T. Navok, *Anal. Biochem.* **128**, 152 (1983); V. Lattanzio, V. V. Bianco, D. Lafiandra, *Experientia* **38**, 789 (1982); V. L. Flohe, G. Niebch, H. Reiber, *Z. Klin. Chem. Klin. Biochem.* **9**, 431 (1971); J. Mager, M. Chevion, G. Glaser, in *Toxic Constituents of Plant Foodstuffs*, I. E. Liener, Ed. (Academic Press, New York, 1980), pp. 265–294.
31. J. K. Dunnick *et al.*, *Fundam. Appl. Toxicol.* **2**, 114 (1982).
32. L. C. Berardi and L. A. Goldblatt, in *Toxic Constituents of Plant Foodstuffs*, I. E. Liener, Ed. (Academic Press, ed. 2, New York, 1980), pp. 183–237.
33. S. P. Xue, in *Proceedings: Symposium on Recent Advances in Fertility Regulation* (Beijing, 2 to 5 September, 1980), p. 122.
34. R. K. Haroz and J. Thomasson, *Toxicol. Lett. Suppl.* **6**, 72 (1980).
35. M. Coburn, P. Sinsheimer, S. Segal, M. Burgos, W. Troll, *Biol. Bull. (Woods Hole, Mass.)* **159**, 468 (1980).
36. C. Campbell, personal communication.
37. G. D. Manners, G. W. Ivie, J. T. MacGregor, *Toxicol. Appl. Pharmacol.* **45**, 629 (1978); G. W. Ivie and D. A. Witzel, in *Plant Toxins*, vol. 1, *Encyclopedic Handbook of Natural Toxins*, A. T. Tu and R. F. Keeler, Eds. (Dekker, New York, in press).
38. J. C. M. Van der Hoeven *et al.*, in *Mutagens in Our Environment*, M. Sorsa and H. Vainio, Eds. (Liss, New York, 1982), pp. 327–338; J. C. M. van der Hoeven, W. J. Lagerweij, I. M. Bruggeman, F. G. Voragen, J. H. Koeman, *J. Agric. Food Chem.*, in press.
39. T. Hirayama and Y. Ito, *Prev. Med.* **10**, 614 (1981); E. Hecker, *J. Cancer Res. Clin. Oncol.* **99**, 103 (1981).
40. M. R. Malinow, E. J. Bardana, Jr., B. Pirofsky, S. Craig, P. McLaughlin, *Science* **216**, 415 (1982).
41. B. N. Ames, *ibid.* **204**, 587 (1979). "Mutagen" will be used in its broad sense to include clastogens and other DNA-damaging agents.
42. H. F. Stich and R. H. C. San, Eds., *Short-Term Tests for Chemical Carcinogens* (Springer-Verlag, New York, 1981).
43. P. Hochstein and S. K. Jain, *Fed. Proc. Fed. Am. Soc. Exp. Biol.* **40**, 183 (1981).
44. D. E. Levin, M. Hollstein, M. F. Christman, E. Schwiers, B. N. Ames, *Proc. Natl. Acad. Sci. U.S.A.* **79**, 7445 (1982). Many additional quinones and aldehydes have now been shown to be mutagenic.
45. S. G. Carmella, E. J. LaVoie, S. S. Hecht, *Food Chem. Toxicol.* **20**, 587 (1982).
46. K. Morimoto, S. Wolff, A. Koizumi, *Mutat. Res. Lett.* **119**, 355 (1983); T. Sawahata and R. A. Neal, *Mol. Pharmacol.* **23**, 453 (1983).
47. H. Kappus and H. Sies, *Experientia* **37**, 1233 (1981).
48. L. Tikkanen, T. Matsushima, S. Natori, *Mutat. Res.* **116**, 297 (1983).
49. P. K. Singal, N. Kapur, K. S. Dhillon, R. E. Beamish, N. S. Dhalla, *Can. J. Physiol. Pharmacol.* **60**, 1390 (1982).
50. A. Kasamaki *et al.*, *Mutat. Res.* **105**, 387 (1982).
51. J. D. Hendricks, R. O. Sinnhuber, P. M. Loveland, N. E. Pawlowski, J. E. Nixon, *Science* **208**, 309 (1980); R. A. Phelps, F. S. Shenstone, A. R. Kemmerer, R. J. Evans, *Poult. Sci.* **44**, 358 (1964); N. E. Pawlowski, personal communication.
52. I. Emerit, A. M. Michelson, A. Levy, J. P. Camus, J. Emerit, *Hum. Genet.* **55**, 341 (1980).
53. *FDA Compliance Program Report of Findings. FY79 Total Diet Studies—Adult* (No. 7305.002); available from National Technical Information Service, Springfield, Va.). It is estimated that the daily dietary intake of synthetic organic pesticides and herbicides is about 60 μg, with chlorpropham, malathion, and DDE accounting for about three-fourths of this. An estimate of 150 μg of daily exposure in Finland to pesticide residues has been made by K. Hemminki, H. Vainio, M. Sorsa, S. Salminen [*J. Environ. Sci. Health* **C1** (No. 1), 55 (1983)].
54. N. K. Hooper, B. N. Ames, M. A. Saleh, J. E. Casida, *Science* **205**, 591 (1979).
55. L. W. Wattenberg, *Cancer Res. (Suppl.)* **43**, 2448s (1983).
56. J. Hoey, C. Montvernay, R. Lambert, *Am. J. Epidemiol.* **113**, 668 (1981); A. J. Tuyns, G. Pequignot, M. Gignoux, A. Valla, *Int. J. Cancer* **30**, 9 (1982); A. Tuyns, in *Cancer Epidemiology and Prevention*, D. Schottenfeld and J. F. Fraumeni, Jr., Eds. (Saunders, Philadelphia, 1982), pp. 293–303; R. G. Ziegler *et al.*, *J. Natl. Cancer Inst.* **67**, 1199 (1981); W. D. Flanders and K. J. Rothman, *Am. J. Epidemiol.* **115**, 371 (1982).
57. E. L. Abel, *Hum. Biol.* **54**, 421 (1982); H. L. Rosset, L. Weiner, A. Lee, B. Zuckerman, E. Dooling, E. Oppenheimer, *Obstet. Gynecol.* **61**, 539 (1983).

57a. R. A. Anderson, Jr., B. R. Willis, C. Oswald, L. J. D. Zaneveld, *J. Pharmacol. Exp. Ther.* **225**, 479 (1983).

58. H. F. Stich and M. P. Rosin, *Int. J. Cancer* **31**, 305 (1983).
59. R. P. Bird, H. H. Draper, P. K. Basrur, *Mutat. Res.* **101**, 237 (1982); M. A. Campbell and A. G. Fantel, *Life Sci.* **32**, 2641 (1983).
60. V. J. Feron, A. Kruysse, R. A. Woutersen, *Eur. J. Cancer Clin. Oncol.* **18**, 13 (1982).
61. T. Suematsu *et al.*, *Alcoholism: Clin. Exp. Res.* **5**, 427 (1981); G. W. Winston and A. I. Cederbaum, *Biochem. Pharmacol.* **31**, 2301 (1982); L. A. Videla, V. Fernandez, A. de Marinis, N. Fernandez, A. Valenzuela, *Biochem. Biophys. Res. Commun.* **104**, 965 (1982); T. E. Stege, *Res. Commun. Chem. Pathol. Pharmacol.* **36**, 287 (1982).
62. M. G. Cutler and R. Schneider, *Food Cosmet. Toxicol.* **12**, 451 (1974).
63. Y. Tazima, in *Environmental Mutagenesis, Carcinogenesis and Plant Biology*, E. J. Klekowski, Jr., Ed. (Praeger, New York, 1982), vol. 1, pp. 68–95.
64. P. N. Magee, Ed., *Banbury Report 12: Nitrosamines and Human Cancer* (Cold Spring Harbor Laboratory, Cold Spring Harbor, N.Y., 1982); P. E. Hartman, in *Chemical Mutagens*, F. J. de Serres and A. Hollaender, Eds. (Plenum, New York, 1982), vol. 7, pp. 211–294; P. E. Hartman, *Environ. Mutagen.* **5**, 111 (1983).
65. Committee on Nitrite and Alternative Curing Agents in Food, Assembly of Life Sciences, National Academy of Sciences, *The Health Effects of Nitrate, Nitrite, and N-Nitroso Compounds* (National Academy Press, Washington, D.C., 1981).
66. H. F. Stich, P. K. L. Chan, M. P. Rosin, *Int. J. Cancer* **30**, 719 (1982); H. F. Stich and M. P. Rosin, in *Nutritional and Metabolic Aspects of Food Safety*, M. Friedman, Ed. (Plenum, New York, in press).
67. L. J. Kinlen, *Br. Med. J.* **286**, 1081 (1983); D. J. Fink and D. Kritchevsky, *Cancer Res.* **41**, 3677 (1981).
68. C. W. Welsch and C. F. Aylsworth, *J. Natl. Cancer Inst.* **70**, 215 (1983).
69. P. Correa, J. P. Strong, W. D. Johnson, P. Pizzolato, W. Haenszel, *J. Chronic Dis.* **35**, 313 (1982).
70. F. B. Shorland *et al.*, *J. Agric. Food Chem.* **29**, 863 (1981).
71. M. G. Simic and M. Karel, Eds., *Autoxidation in Food and Biological Systems* (Plenum, New York, 1980).
72. W. A. Pryor, Ed., *Free Radicals in Biology* (Academic Press, New York, 1976 to 1982), vols. 1 to 5.
73. H. B. Demopoulos, D. D. Pietronigro, E. S. Flamm, M. L. Seligman, *J. Environ. Pathol. Toxicol.* **3**, 273 (1980).
74. F. Bischoff, *Adv. Lipid Res.* **7**, 165 (1969).



NOTE: If you would like to receive a copy of the references with complete titles of the articles, please send me a stamped self-addressed envelope, and a copy will be mailed to you.

Mr. RITTER. The point that Dr. Ames is making is that there are ways in which the American public can address the subject of better health. There are ways in which the Government, through educational and regulatory procedures can address the subject of better health. However, he is making a point that there are potential risks that need to be brought into the overall equation and perhaps to be compared with some of the risks that we are dealing with.

He talks about naturally occurring carcinogens in foods that we eat. These are essentially natural, nature's pesticides for helping plants to avoid certain diseases and pests. These are simply chemicals that exist in certain foods that we eat.

I would like to just quote a little bit here. He talks about a variety of these foods, "16 examples above, plus coffee—discussed below—illustrate that the human dietary intake of 'nature's pesticides' is likely to be several grams per day—probably at least 10,000 times higher than the dietary intake of manmade pesticides." By the way, chocolate is right in there as a marvelous bad actor.

This is a question of significance and comparing and coming up with data that just now is isolating these chemicals, coming up with data that can help the American people to pick and choose and create a diet for themselves which may provide years in extended lifespan for this population. We have learned that dietary aspects of human health are exceedingly important. We have watched populations living in Japan having one set of lifespans moving to the west coast of the United States, and in one generation, assuming the American lifespan. I might add, it is some nearly 10 years shorter in this country. That has been associated with diet. Now we are finding out the precise chemicals that are involved in these various dietary intakes. In the risk assessment process, we can provide the public and the people with the significance of what all this means at some point so that they can make better decisions in their own lives.

We are talking about things that we consume on a very substantial basis, like burnt foods. We are talking about grams and ounces. We are talking about fats which have been implicated in the oxidative mechanism of cells running out of control in the cancer process, and foods that have been implicated in the degenerative disease processes of aging of which cancer and heart disease are part and parcel.

Mr. MCGRATH. Will the gentleman yield?

Mr. RITTER. Yes, I would be happy to yield to my colleague.

Mr. MCGRATH. First of all, let me ask unanimous consent that my opening statement be inserted in the record, Mr. Chairman.

Mr. SCHEUER. Without objection, so ordered.

Mr. MCGRATH. First of all, let me congratulate my colleague for being the outstanding and outspoken Member of the Congress on risk assessment and risk management. I was just struck by one of the comparisons that you made regarding the burning of food and the striking of matches in relationship to a particular problem that I have in my district. Seemingly, we have this capacity to produce garbage, and we frankly can't find a way to dispose of it in any manner which is environmentally safe. We have land fills, and we have resource recovery plants——

Mr. RITTER. Most people would consider it safe if you move it to somebody else's district, or back yard, as the case may be.

Mr. MCGRATH. That is correct. We are moving it to New Jersey now. That is the safest place.

The point is that at some time when the local government officials attempted to open this resource recovery plant, a particulate of dioxin was emitted to the extent, I think it was one-tenth of so many parts per billion, something that was unmeasurable a few years ago. I am told, I have no great scientific background on this, but I am told that more dioxin is emitted as you strike a match to light a cigarette or, as you said, more dioxin is emitted as you cook a steak or maybe you consume dioxin when you eat that steak.

Mr. RITTER. I wasn't speaking specifically of dioxin, but the gentleman is making a very significant point. It is the most famous case of nonresource recovery in the country, the most famous case of nonrecycling, the most famous case of lack of putting hazards in perspective, and it is interesting to note that it is in your district. Have fun!

Mr. MCGRATH. My point simply is that I think that if people were better informed as to what the risks are that they could better make more informed judgment as to what risks they would rather take. I think this bill goes a long way in establishing a risk assessment system within our government so that the public which has a right to know can make those value judgments which they must make. As I think all of us understand, sooner or later, if you test everything to the extent that we are able to measure it today, we are going to find that there is some risk in doing everything that we do, whether we step off a curb or ride a bicycle or whatever.

Mr. RITTER. The gentleman is absolutely correct. At some point, as chemical detection techniques become more and more sophisticated, we can detect parts per billion and parts per trillion and who knows beyond that. In one little hunk of material there is a heck of a lot of molecules. Avogadro's number is not that well known to the political community, but it is an exceedingly large number, and you can always get at least one or two parts in there when you are talking about a number like 10 to the 24th power.

Mr. MCGRATH. I just wanted to assure you that I find this bill to be extremely interesting. It ought to be looked at by the entire House and acted upon as quickly as possible so that we can get this mechanism working.

Mr. RITTER. I thank the gentleman for his statement of support. There is some opposition. I am not sure the opposition is in the House necessarily, but there is some opposition that is essentially seeking no risk assessment policy or risk comparison policy, that seeks a kind of zero risk. I submit that if we regulate on that basis, not only will we turn off each and every valve of the modern, industrial, technological society which has brought us the greatest, most extensive lifespan in the history of this country, but we are going to be unhealthy or we are going to be unsafe, because the resources that we apply will be applied randomly and helter-skelter in regard to what the latest program on "60 Minutes" was.

We have to lie somewhat above that plane in making some of these exceedingly important decisions.

Mr. McGRATH. Here is a risk I choose to take.

[Displaying cigar.]

Mr. RITTER. I want to let you know that the chairman, in sitting next to you, is probably taking almost as large a risk as you are if you are not inhaling. He might be inhaling it.

Mr. SCHEUER. May I say that in cognizance of that risk that he is imposing upon me willy-nilly, he had the good grace to offer me the advantage of sharing in the initial risk and not enjoy just the detriment of the slip stream without the pleasure of the initial use.

[Displays cigar.]

[Laughter.]

Mr. RITTER. I submit that——

Mr. SCHEUER. For which I thank my colleague publicly.

Mr. RITTER. I would like to thank my colleague, too, for his comments. I think they are right on target.

I submit that if people are going to take certain voluntary risks that are orders upon orders of magnitude, maybe a thousand or million times greater than some of the societal risks, that at least they should know about it. We can't force them, but I think they should know about it. They should have some idea that smoking one cigar is probably more risky than spending 10 lifetimes next to Three Mile Island.

Mr. SCHEUER. Why do you say we can't force them? A large part of the work of this Congress is engaging in the debate over whether we should or shouldn't force them in a thousand different ways to reduce or eliminate their risks involuntarily. The whole question of safety glass and collapsible steering wheels and shoulder harnesses and air bags is one.

Mr. RITTER. I understand. We do all the time in terms of societally or corporate imposed risks, but I am thinking in terms of the voluntary risks, the lighting up, the eating of high fat foods, the drinking, the driving fast and not buckling seat belts. I think in this country it is pretty difficult to force people from the Government side to change their habits.

Let me point out one additional thing. The news is not all bad in Dr. Bruce Ames' Science Magazine article. He does talk about a series of steps, dietary intakes, that can be adopted which are anticarcinogenic. I think these are the kinds of pieces of information that should enter into the picture too. I don't think there is anybody here from the carrot industry, but beta-carotene is a real fine actor. Vitamin C has been shown in recent experiments with laboratory animals to have an anticarcinogenic effect when exposed to carcinogens and anticarcinogens at the same time. We are learning a great deal.

All I am saying is, and I will close on this note, that as we learn a great deal about hazards, there are two ways the society can approach them. It can throw up its hands and say, oh my God, another risk. Or it can say, we understand to some extent the level at which this hazard is impacting on us or on various populations that may not be us. We can take some consolation in the fact that our understanding allows us the opportunity to either do something about it, depending on significance, or not, to regulate or not to regulate, to regulate at a certain level or at some other level.

I think that is the real bottom line. We are simply arguing for a greater degree of science intelligence in this most science-based problem area.

I thank the chairman for his forbearance and for letting me run over time. I thank him also for his leadership in this area.

[The prepared statement of Mr. McGrath follows:]

STATEMENT OF HON. RAYMOND J. MCGRATH

Thank you, Mr. Chairman.

I want to join the chairman in welcoming our witnesses here this morning. I also want to extend a special welcome to our colleague, Representative Don Ritter, who is the author of the legislation which is the subject of this hearing. Don has been interested in risk assessment since he came to Congress and has pursued legislation in this area diligently and persistently.

H.R. 4192 raises some substantive, important issues for the Congress and the regulatory agencies to consider. I think we should acknowledge that some government regulation does have a place in our complex, technological society. Government regulation is, indeed, a coming together of social priorities, economic factors, and scientific data. No one really questions the need for regulation which protects the health and environment of our nation.

What we do question is the scope of the regulation, its expense, lack of accountability and the complicated manner in which some of the regulations are drafted. We all know that the public has called for a far more rational approach to regulations, and the public also wants to be informed of the risks facing them in a manner which can be understood by the average person. I know that these were two of Don's goals when he drafted this legislation and I look forward to the comments of our witnesses on the bill.

Mr. SCHEUER. I want to thank our colleague from Pennsylvania for his most interesting statement and his most thoughtful and challenging and stimulating statement. He certainly has been one of the most innovative and thoughtful Members of either the House or the Senate in this field. He has made a tremendous contribution to our thinking, and I am sure he will continue to.

The hour is late and we do have a list of witnesses, so I am not going to carry on now with any significant number of questions. Let me ask you just one question to sort of bring this down to specifics.

Take the subject of acid rain. On the one hand, we have those who say, we can't do anything until we know everything, before we can make a science-based judgment. On the other hand, there are those who say we shouldn't have to wait until we know everything because the fact is we never will know everything, but we probably know enough now to do something. There are a number of reasonably prestigious groups who have said that on the subject of acid rain we ought to do something, that we may not know enough to do everything, to take Herculean measures that would cost industry hundreds of billions of dollars, but we know enough to take certain minimal steps.

The National Academy of Sciences has said this very clearly. The Senate Environment Committee has said this; they reported out a bill. The National Governors' Association has said this, and the Clean Air Coalition, composed of all the environment groups, has said this. On the other hand, the President's designated risk assessor, the Office of Management and Budget, thinks to the contrary. There have been several occasions upon which Mr. Ruckelshaus has come up with some kind of a minimum, modest proposal for dealing with acid rain, and they have beaten him down and said no, the state of our knowledge doesn't enable us to go ahead.

Now, from your point of view, being an objective guy, as we all are objective, especially coming from western Pennsylvania, as you do——

Mr. RITTER. No, I am actually from northeast Pennsylvania, Allentown, Bethlehem, and Lehigh Valley area.

Mr. SCHEUER. Well, coming from the Bethlehem and Lehigh Valley area makes you even more objective than most of us. As a matter of intellectual and ethical and moral challenge, he would have to rise above his parochial interests.

Where do you come down on this and how would you apply the risk assessment process to this problem and the quality and the quantity of the body of evidence that has been adduced over the last many years? How do you come down on the value judgment that the Senate Environment Committee has made, the National Academy of Sciences has made on the one hand and the value judgment that the President and his risk assessor, the OMB, have made on the other hand.

Mr. RITTER. I think that is a very interesting question. I don't think it is just some kind of a dichotomy between the Senate Environment Committee and the President and his administration. I think the recent vote in our Health Subcommittee in the Energy and Commerce Committee right here in the House has denied what was thought to be the most consensus approach to acid rain.

Let me say that I think the question is extremely important because it draws a line between risk assessment, putting hazards in some perspective, and risk management. Right now, we are on a sharp upward curve about what we know about acid rain. Anybody who wanted to do acid rain research in the last 5 years had been funded by the Federal Government or the Electric Power Research Institute or the National Coal Association. There is a tremendous amount of information coming on line, and we are in an assessing phase, learning more and more.

I am not sure that risk assessment per se has yet been applied to the acid rain problem in terms of human health. I am not sure that people have taken it that far because the connections are not that strong on the human health side, or at least they are not that known, and sometimes when they are not that known, it indicates that they are not that strong. Where we find it is in assessing the health and well being of environmental qualities such as our streams and our lakes and our forests.

Between the National Academy report and research coming on line that agrees and doesn't agree at times with local source contributions to this overall question, we are on this sweeping upward curve. I am one of those people who believes that we do know enough to begin to take action. So, in a way, we are already immersed in the assessment phase. We are continuing to assess, and that will go on. However, we have entered the risk management phase, and that is different from my bill.

The risk management phase is what we have witnessed in the recent markup in the Health Subcommittee of the Energy and Commerce Committee where, by a close vote, the Waxman-Sikorski bill was defeated. That has a variety of factors, there is local economics and regional economics, local and regional politics, and regional differences on who gets to pay and who doesn't get to pay. That is not what my bill is about.

My bill is to say, OK, have we really done the risk assessment side of acid rain? Have we really put the acid rain into some kind of environmental risk context? You can answer that question for yourself. I think we have gone a long way to do that, and I think we are ready to do something. The question of how to accomplish it is the risk-management question, and that is really separate from our bill.

Mr. SCHEUER. We enjoyed your testimony and benefited by it.

Mr. RITTER. Thank you.

Mr. SCHEUER. Mrs. Schneider.

Mrs. SCHNEIDER. Mr. Ritter, I wanted to ask you if you were aware of the efforts of this committee to take some of the money from the proposed budget and put it into risk assessment for DOE's budget. I don't know if you are aware of it, but the proposal had been to zero out both risk assessment and epidemiological studies in the DOE budget. Were you, by chance, aware of that?

Mr. RITTER. I wish you had made me aware because I would have joined you in fighting it tooth and nail.

Mrs. SCHNEIDER. It is very frustrating because we just learned the other day that we succeeded here in committee but the Appropriations Committee once again zeroed it out. I think the shortsightedness of that we can easily agree on.

Mr. RITTER. The gentlelady from Rhode Island is making a very important point on behalf of this bill. The problem is that in the Appropriations Committee the idea of risk assessment, its importance as a kind of underlying feature to how we protect health, safety and environment in America is not understood. Why isn't it understood? Because it is a virtually new area of science/social science. It is just coming to the foreground.

What this bill would do is bring this out more into the open, encourage the more innovative and creative developmental side of the techniques, encourage a greater communication of the emerging tool for the regulatory tool box, and, I believe, make it easier for people in the Appropriations Committee who are nonscientists doing the best job that they can to understand what it is this is about.

Mrs. SCHNEIDER. I was anxious to know what kind of support you have received from people outside of the Congress. Have there been any coalitions or scientific groups that have signed off or who have been promoting your legislation?

Mr. RITTER. Yes. Maybe that is another interesting idea. Maybe we should formalize that process. We have had some very substantial support out of the scientific community, what I would refer to as the consensus scientific community. You always have certain scientists on one side of an issue and certain others on another, but I think in terms of consensus science from the professional societies to the various people involved in health, safety, and environment work, we have received some very excellent support from a broad cross section.

The gentlelady wasn't here, but I did admit that there are certain elements out there that don't wish to see some kind of legislative progress in assessing risk and comparing risk and putting hazard in perspective. I guess we will hear from some of them today. I certainly don't want to make their argument for them. I hope they will see that this is an objective attempt to make science and policy a more effective part of our Government and our regulatory procedures.

Mrs. SCHNEIDER. I think that the appeal that your particular piece of legislation has is that it appeals to a scientific basis as opposed to emotional decisionmaking which, as we know, is the name of the game here in Congress because of the lack of scientists who serve in Congress and because of the failure of the scientific community outside of Congress to communicate and to lobby their wishes. As a result, we don't have appropriate data bases on which to make decisions, and as a result, we continue to follow along the lines of crisis management. We wait until the crisis occurs and the obvious evidence is there, and then often it is more costly and too late for either the environment or public health.

Mr. RITTER. All I can say is amen. Thank you for your comments.

Mrs. SCHNEIDER. All right. I don't have any further questions. Thank you.

Thank you, Mr. Chairman.

Mr. SCHEUER. Congressman Tim Valentine.

Mr. VALENTINE. I don't have any questions. Thank you, Mr. Chairman.

Mr. SCHEUER. All right. Thank you very much, Congressman Ritter.

Now, we will go right to our first panel, Dr. Nicholas Ashford, director of the Center for Policy Alternatives at MIT; Dr. Joseph Rodricks, Environ Corp. of Washington; and Dr. Peter Huber of the U.S. Supreme Court. We will hear first from Nicholas Ashford, director of the Center for Policy Alternatives at MIT in Cambridge. Why don't you take about 7 or 8 minutes, Dr. Ashford, and sum up your testimony and then, I understand, you are under time pressure and have to catch a plane, we will have some questions for you and let you be gone.

STATEMENT OF DR. NICHOLAS ASHFORD, DIRECTOR, CENTER FOR POLICY ALTERNATIVES, MASSACHUSETTS INSTITUTE OF TECHNOLOGY

Dr. ASHFORD. Thank you, Mr. Chairman.

I am pleased to be here once again to discuss these issues. I have followed the various bills presented by Congressman Ritter in the area of risk assessment and have previously testified on an earlier version of this legislation. While the present bill, in my view, reflects some improvement over prior versions, I have fundamental reservations about various aspects of the proposed bill. I would like to structure my remarks around four themes:

One is the validity of the premises and assumptions upon which this bill is based, what you call your findings. Second, the limitation of risk assessment methodologies from a technical perspective, particularly so-called comparative risk assessment exercises. Third, the question of whether, as has been asserted, it is in fact realistic to separate the risk assessment exercise into a technical component and a so-called value laden, evaluative, management component, a policy component, if you will. Can you really separate those things? I think you can't. Fourth, the likely, very important, perhaps unintended and adverse political consequences of this legislation should it pass.

With regard to the first set of issues, it is the premises and assumptions on which this bill is based, there is mentioned in section 102(a)(6) of the bill a concern for the need to balance these kinds of risks against the economic and other social concerns. While the finding is correct that some legislation requires this, for the most part, environmental health and safety legislation does not require such a balancing. In fact, the balance, as the Supreme Court has designated in the case of OSHA, for example, has already been done by the Congress.

Unless, in my view, the purpose of this legislation is to create a basis for mobilizing public support for changing the existing legislation, that is, restriking the balance, then I think this exercise is misguided.

Other places in the bill talk about the great promise of comparative risk assessment and, as I will explain shortly, technical limitations when you look clearly at what that means, render that objective inoperable.

Finally, as I have indicated, the suggestion that the term risk assessment can be nicely separated into a risk analysis exercise and a risk evaluation exercise unrealistically assumes that the techniques and the methodologies utilized in technical risk analysis are value-free. We are asked that here is science on the one hand and here is policy on the other hand and the so-called move towards better science which everybody should love and embrace somehow has a value free component.

I believe, and in 10 years of involvement in this area, that the so-called move to better science is really a way to impose a different set of value assumptions on the exercise. It is a policy camouflaged as scientific enhancement.

Now, on the point about risk assessment methodologies and their limitations, I presented detailed testimony elsewhere and I have included that testimony here on this bill about the limitations of the techniques utilized for assessing environmental health and safety risks. Let me tell you, Congressman Scheuer, that I would be the person who would benefit from this bill as the director of the Center for Policy Alternatives. We do a great deal of technical risk assessment for the Government, for industry, for private concerns. We, in fact, are at the cutting edge of developing the methodologies that Congressman Ritter thinks will save us. Therefore, we are interested in advancing the science.

At the same time, I believe that the vehicle presented here is totally inappropriate for enhancing the scientific base of what we need and I believe it has other agendas in mind.

On the issue of comparative risk assessment, I want to make a very important point which I have made elsewhere, and that is the risk estimates, the technical exercise you perform, are often so uncertain that it is highly misleading to present them as single point estimates. That is, as a single number, such as the number of cancers resulting from an exposure. You will hear from subsequent witnesses, probably Professor Wilson of Harvard, that you can compare smoking with getting cancer from a pesticide with riding a motorcycle.

Unlike rock climbing, you can't try cancer on to see if you like it. The comparative risk assessment exercise is fraught with this problem. Risk is not a single number. It is a probability distribution and that probability distribution or a risk profile, is very different for substances which are carcinogens and substances which are classical toxins like lead.

Comparative risk assessment, and I speak now technically, from a competency point of view, makes sense only for comparing risks of an essentially identical nature. You could compare the risks from benzene, nitrobenzene, and chlorobenzene. You cannot compare the risk profile meaningfully of benzene with lead, let alone rock climbing with exposure to a carcinogen. It makes little scientific sense. Unless you want to simplistically use single numbers, such as the chance of dying from a motorcycle is 10 to 5, compared to the chance of dying from a pesticide, 10 to 6, which is absolutely a bogus comparison, unless you insist on doing that, comparative risk assessment makes little sense.

The insistence that the risk assessment exercise can be separated into a risk analysis and risk evaluation exercise really falls on its face. In a recent study I published in the Harvard Environmental Law Review which is summarized in Science Magazine, I investigated the distinction between determinations of science, so-called better science, and the determinations of science policy as practiced by EPA, OSHA, and the CPSC. In this case, it was concerning the carcinogenicity of formaldehyde.

What the history reveals is that value judgments, policy judgments become camouflaged as scientific determinations and that there is really no value free determination concerning the resolution of technical problems beset by great uncertainty. I want to emphasize that risk assessment cannot be separated into a value free technical exercise and then nicely and neatly followed by a value component called risk evaluation.

The acceptability of risk, this term, acceptable risk, must extend to the acceptability of uncertainty, and the calculations of uncertainties by their very nature are based more on science policy determinations than on hard science.

Finally, the suggested increased reliance on outside experts and the use of technical advisory committees, of which I have served as chairman at prior times, can lead to either good or bad results depending upon the extent to which the choice of the experts is politically motivated. I attach for your reference a publication in this area.

Let me talk about what I believe to be the practical consequences of this legislation should it pass. In my view, this legislation simply represents an attempt to reorient the fundamental mandates of the regulatory agencies. If that is the desire of the Congress, I suggest that they meet the challenge head on and not through the vehicle of this bill. This legislation provides new tasks for but no additional funds to the regulatory agencies already beleaguered by budget cuts, a loss of technical personnel, and a backlog of real regulatory problems to address.

The National Academy of Sciences and the Office of Technology Assessment have already done studies about risk methodology development. The regulatory agencies themselves have sponsored numerous workshops and conferences on this subject. I don't believe we need a formalized prodding for risk assessment methodologies to develop. The technical information which this bill will hope to generate and assemble offers little in addition to what is already known.

The not so hidden agenda of this legislation is embodied in the expectation of the report required to be produced containing suggestions for changes in statutory language and organizational structure.

I submit further that leaving to the President the power to appoint the lead or coordinating agency to oversee this exercise is to inappropriately transfer congressional power to the executive branch. I ask, does Congress really want to do this? The Office of Management and Budget or the Office of Science and Technology Policy are not appropriate agencies for deciding scientific matters. If by some chance, this legislation is to pass, I would certainly recommend designating a nonregulatory agency, not close to the President, to oversee the exercise. I believe an agency whose purpose is scientific—if the purpose is better science, then one ought to consider an agency such as the National Institute for Environmental Health Sciences as a more appropriate choice for assessing risk-analysis methodologies. This choice should be mandated by the Congress, not left to the discretion of the President.

In summary, I would urge Congress to put this latest version of Mr. Ritter's bills to rest and instead search for constructive, alternative ways to strengthen the Federal scrutiny of serious environmental, health, and safety risks.

Thank you very much.

[The prepared statement of Dr. Ashford follows:]

Commentary on the Risk Assessment Research and Demonstration Act of 1983[*]

H.R. 4192

Nicholas A. Ashford,[**]+ Ph.D., J.D.

I am pleased to appear today to offer commentary on H.R. 4192. I have followed the evolution of the various bills presented by Congressman Donald Ritter in the area of risk assessment and have previously testified on an earlier version of this proposed legislation (see Attachment A). While the present bill reflects some improvement over prior versions, I have fundamental reservations with various aspects of the proposed bill. I would like to structure my remarks around four themes:

1. The validity of the premises and assumptions upon which this bill is based;
2. The limitations of risk assessment methodologies, particularly comparative risk assessment;
3. The question of whether it is realistic to separate the risk asessment exercise into technical and value judgments; and
4. The likely, though perhaps unintended adverse political consequences of the legislation.

Premises and Assumptions

In Section 102(a)(6) of the Bill, it is asserted that

> these [regulatory] decisions may involve an assessment of risks to human life, health and the environment and a balancing of those risks against the economic and social consequences of controlling them. (emphasis added)

---

[*] Testimony presented before Subcommittee on Natural Resources, Agriculture Research and Environment of the Committee on Science and Technology on May 17, 1984.

[**] Director of the Center for Policy Alternatives and Associate Professor of Technology and Policy at MIT.

While this assertion is technically correct through use of the word "may", most environmental, health and safety regulation does not require such a balancing. Most environmental regulations are premised on either health based standards or standards limited by technological feasibility. In the OSHA Cotton Dust Case, in rejecting a demand for cost-benefit analysis the Supreme Court correctly stated that the balancing between health risk and economic factors had already been done by the Congress. Congress has, in fact, addressed the question of balance in all environmental regulations.

In Section 102(a)(7) of the bill, it is asserted that

> improving the quality of the scientific component of such decisions is an important aspect of securing the public's ability to properly weigh the social and philosophical values intrinsic in them;

Unless the purpose of this legislation is to create a basis for mobilizing public support for changing the existing legislation concerning health risks, the exercise is misguided.

In Section 102(a)(8) of the Bill, it is stated:

> analysis of the comparative risks to health and welfare can assist in setting public policy objectives and gaining public understanding of regulatory management decisions. (emphasis added)

As I will explain shortly, comparative risk assessment is unlikely to achieve this objective, which again appears to be motivated by a desire to mobilize support for reexamining the fundamental regulatory mandates in the environmental health and safety area.

Finally, in Section 104(d) of the bill, the suggestion that the term "risk assessment" encompasses both technical risk analysis and risk evaluation (i.e., valuing the achievement of risk reduction) unrealistically assumes that the techniques and methodologies utilized in technical risk analysis are value free.

The Limitations of Risk Assessment Methodologies

In my prior testimony on H.R. 4939, I presented detailed commentary on the technical limitations of techniques utilized for assessing environmental, health and safety risks. I have attached that commentary for your reference, but would like to reemphasize the fact that risk estimates are often so uncertain that it is highly misleading to present them as single point estimates -- i.e., a single number, such as the number of cancers (see Attachment B). Risk is not a single number; it is itself a probability distribution. That probability distribution or "risk profile" is very different for carcinogens and classical toxins such as lead. Comparative risk assessment makes sense only for comparing risks of an essentially identical nature, such as those from benzene, nitrobenzene, and chlorobenzene. It makes little scientific sense to compare the risk profile from a carcinogen producing death to the risk profile for lead producing non-lethal neurological damage. Unless you use single point estimates to compare risks -- a practice which is methodologically without foundation -- comparative risk assessment is not possible in a meaningful way.

Therefore, the definition for comparative risk assessment in Section 104(e) of the bill, which anticipates that there can indeed be a procedure for comparing a sizeable number of risks is wishful thinking and not practically achievable.

Risk Analysis and Risk Evaluation

In Section 102(e) risk assessment is defined as

> a multistep process consisting first of a scientifically based risk analysis, which concentrates on the identification, probability, and consequences of risk, followed by a risk evaluation which is more judgmental in nature and concentrates on decisions defining acceptable levels of risk.

In a recent study which I published in the Harvard Environmental Law Review and in a summary from Science, (see Attachment C) I investigate the distinction between determinations of science and determinations of science policy as practiced by EPA, OSHA and CPSC concerning the carcinogenicity of formaldehyde. What the history reveals is that value judgments become camouflaged as "scientific" determinations and that there is really no value-free scientific determination concerning the resolution of problems beset by great uncertainty.

Risk assessment cannot be separated into a value-free technical exercise and then be followed by the value component called risk evaluation. The acceptability of risk must extend to the acceptability of uncertainty, and the calculation of uncertainties by their very nature are based more on science policy determinations than on hard science. This relates to the fact that risk is not a single point estimate. It is a distribution of probabilities reflecting scientific uncertainty.

Finally, the suggested increased reliance on outside experts and the use of technical advisory committees can lead to either good or bad effects, depending upon the extent to which the choice of those experts or members of the advisory committees are politically motivated. I attach for your reference a recent publication concerning the possible misuse of technical advice in the environmental, health and safety area. (Attachment D)

Practical Consequences of the Legislation

In my view, this legislation represents an attempt to reorient the fundamental mandates of the regulatory agencies. If that is the desire of the Congress, I suggest that they meet that challenge head on and not through the vehicle of this bill. This legislation provides new tasks for, but no additional funds to the regulatory agencies already beleagured by budget cuts, a loss of technical personnel and a backlog of regulatory problems to address. The National Academy of Sciences and the Office of Technology Assessment have already provided studies of risk assessment methodologies. The regulatory agencies themselves have sponsored numerous workshops and conferences on this subject. The technical information which this bill would hope to generate and assemble offers little in addition to what is already known. The not so hidden agenda of this legislation is embodied in the expectations of the report required to be produced containing suggestions for changes in statutory language and organizational structure (Section 107(a)(7) and Section 108(a)(4&5).

I submit that leaving to the President the power to appoint the lead or coordinating agency to oversee this exercise is to inappropriately transfer Congressional power to the Executive branch. I ask, does Congress really want to do this? This Office of Management and Budget and the Office of Science and Technology Policy are not appropriate agencies to decide scientific matters. If by some chance this legislation is to pass, I would recommend designating a non-regulatory agency not close to the President to oversee the exercise. I believe an agency whose purpose is scientific, such as the National Institute for Environmental Health Sciences, would be a far more appropriate choice for assessing risk analysis methodologies. This choice should be mandated by the Congress, not left to the President.

In summary, I would urge Congress to put this latest version of Mr. Ritter's bills to rest and instead search for constructive alternative ways to strengthen the federal scrutiny of serious environmental, health and safety risks.

ATTACHMENT A

THE LIMITATIONS OF COMPARATIVE RISK ASSESSMENT IN DECISIONS CONCERNING HEALTH, SAFETY, AND THE ENVIRONMENT

Nicholas A. Ashford, Ph.D., J.D.* and Dale B. Hattis, Ph.D.**

Today I am pleased to present testimony prepared by myself and my colleague, Dr. Dale Hattis, at MIT's Center for Policy Alternatives. The views are our own, however, and do not necessarily represent those of MIT.

H.R.4939 provides for a federal mechanism within the Office of Science and Technology Policy for assessing the comparative risks involved in actions in scientific, technological, and related fields. The Center for Policy Alternatives has recently completed a survey of agency studies identifying the benefits of environmental, health, and safety regulation and we wish to have the published report entered for the record in these proceedings. The benefits of regulation can often be expressed in terms of a reduced risk of adverse health, safety, or environmental effects and therefore our findings may be of special interest to you.

---

*Nicholas A. Ashford is Assistant Director of the Center for Policy Alternatives and Associate Professor of Technology and Policy at MIT.

**Dale Hattis is a Research Associate at the Center for Policy Alternatives at MIT.

Testimony presented before Subcommittee on Science, Research, & Technology of the Committee on Science and Technology, on H.R. 4939, U.S. House of Representatives, May 14, 1980.

AT THE CENTER WE HAVE BEEN EXTENSIVELY INVOLVED WITH ISSUES DIRECTLY RELATED TO THE DESIGN OF REGULATORY POLICY AND HAVE PERFORMED MANY RISK ASSESSMENTS. WHILE WE RECOGNIZE THE IMPORTANCE OF IMPROVING THE MANAGEMENT OF ENVIRONMENTAL HEALTH AND SAFETY RISKS, WE DO NOT BELIEVE THAT THE MECHANISMS OFFERED IN H.R.4939 WILL RESULT IN SUBSTANTIAL IMPROVEMENT. FURTHERMORE, THE UNINTENDED CONSEQUENCES OF THE PROPOSED EFFORT MAY ACTUALLY WORSEN THE SITUATION.

THE MAJOR POINTS WE WOULD LIKE TO STRESS ARE THE FOLLOWING:

RISK ASSESSMENT, UNLIKE ANALYSES OF ENGINEERING COST ESTIMATES, IS IN AN EXTREMELY PRIMITIVE STATE-OF-THE-ART. SERIOUS PROBLEMS OFTEN EXIST REGARDING THE AVAILABILITY OF THE SCIENTIFIC AND TECHNICAL INFORMATION OR EXPLANATORY THEORY NECESSARY TO MEASURE OR TO PREDICT THE EFFECTS OF EXPOSURE TO HAZARDS, I.E., TO PERFORM A RISK ASSESSMENT. ESTABLISHING A CENTRAL FACILITY WITHIN OSTP WILL NOT REDUCE THE INHERENT DIFFICULTY OF THE TASK. A LIMITED EFFORT MAY WELL RESULT IN OVERSIMPLIFICATION AND NEGLECT OF CONCERNS WHICH ARE MORE LIKELY TO BE UNDERSTOOD BY THE SPECIALIZED REGULATORY AGENCIES.

SOME OF THE DIFFICULTIES IN PERFORMING RISK ASSESSMENTS ARE DISCUSSED BELOW.*

---

*THE READER MAY WISH TO SKIP TO THE NEXT MAJOR POINT ON PAGE 6.

CAUSE-AND-EFFECT IS HARD TO DEMONSTRATE

THE RELATIONSHIP BETWEEN EXPOSURE TO A HEALTH OR SAFETY HAZARD AND THE HARM THAT IT CAUSES IS OFTEN DIFFICULT TO ESTABLISH. THIS MAY BE THE CASE BECAUSE OF (1) A TIME LAG (LATENCY) BETWEEN THE INITIAL EXPOSURE AND THE APPEARANCE OF HARM, (2) THE EXISTENCE OF CONFOUNDING OR INTERVENING CAUSAL FACTORS, OR (3) IMPERFECT DATA. WHERE THE RELATIONSHIP BETWEEN EXPOSURE AND HARM IS HARD TO ESTABLISH, IT IS EQUALLY DIFFICULT TO PROJECT HOW A REGULATION MIGHT AFFECT THE DEGREE OF HARM.

FOR EXAMPLE, IT TOOK MANY YEARS OF EXPOSURE TO ASBESTOS FOR ASBESTOS WORKERS TO DEVELOP STATISTICALLY SIGNIFICANT INCREASES IN LUNG CANCER. SIMILARLY, OTHER CHRONIC HAZARDS WHICH HAVE COME UNDER CONTROL RECENTLY MAY NOT GIVE RISE TO DIRECTLY MEASUREABLE HEALTH BENEFITS FOR YEARS TO COME. CONFOUNDING OR INTERVENING CAUSAL FACTORS, SUCH AS THE IMPOSITION OF THE 55 MPH SPEED LIMIT, HAVE COMPLICATED THE MEASUREMENT OF THE EFFECTIVENESS OF MOTOR VEHICLE SAFETY STANDARDS IN REDUCING INJURIES AND FATALITIES. THE MOVEMENT OF PEOPLE FROM PLACE TO PLACE OBSCURES THE LONG-TERM EFFECTS OF LOCAL AIR POLLUTION ON CHRONIC LUNG DISEASE.

THE SHORTAGE OR NONEXISTENCE OF EPIDEMIOLOGICAL DATA

EPIDEMIOLOGY IS THE EMPIRICAL, STATISTICAL STUDY OF THE relationships between diseases and the exposure to their causes. While epidemiology can sometimes be very useful in understanding how regulation might reduce the costs of disease, there are serious practical limits on use of this method. For example, if a substance is newly identified as a health hazard in laboratory studies or by other means, there is only a small chance that anyone has previously studied the exposure to, or the effects of, that substance on human populations. In fact, there are very few studies of working populations, even though they are usually the highest exposed groups. Chance observations of increased disease or injury often lead to a search for the causal factor, but an absence of historical exposure data often makes the search difficult. Furthermore, most populations are exposed to multiple hazards, and it is often not possible to isolate the effects of any one of them. Finally, it is not feasible or acceptable to test new potential hazards by intentionally exposing large numbers of people to them.

Limitations of Models for Environmental Pollutant Diffusion and Transport

In many cases, little is known about how a hazardous substance moves from a source through the environment or about how it degrades or reacts with other substances that may be present. The mode of transport, the length of time involved, how far a substance moves, and what happens to it as it moves

ARE OFTEN ALL UNKNOWNS. FOR EXAMPLE, ACID RAIN IS THOUGHT TO ARISE FROM SULFUR AND NITROGEN OXIDES FROM INDUSTRIAL PROCESSES AND FUEL COMBUSTION, COMBINING WITH WATER IN THE ATMOSPHERE. CURRENTLY, THERE IS ONLY A MEAGER UNDERSTANDING OF HOW THESE COMPOUNDS MOVE THROUGH THE ATMOSPHERE OR HOW THEY REACT CHEMICALLY AS THEY DO. THUS, THERE IS CONSIDERABLE CONTROVERSY ABOUT WHAT KIND OF EMISSIONS SHOULD BE REDUCED, WHERE AND HOW, IF THIS SERIOUS ENVIRONMENTAL PROBLEM IS TO BE BROUGHT UNDER CONTROL.

DOSE-RESPONSE UNCERTAINTIES

ESTIMATING BENEFITS FROM REGULATION IS COMPLICATED BY PROBLEMS IN RELATING THE EXPOSURE TO A HAZARD TO ITS HEALTH EFFECTS. OFTEN, RELIABLE DOSE-RESPONSE DATA ARE AVAILABLE ONLY FOR RELATIVELY HIGH EXPOSURE LEVELS. EXTRAPOLATION OF THESE DATA OFTEN SUGGEST THAT SIGNIFICANT HEALTH EFFECTS WILL OCCUR AT THE LOWER DOSES TYPICAL OF OCCUPATIONAL OR ENVIRONMENTAL EXPOSURE, BUT CONTROVERSY EXISTS OVER THE PROPER MODE OF EXTRAPOLATION. THEORETICAL MODELS HAVE BEEN PROPOSED TO SUPPORT VARIOUS EXTRAPOLATION PROCEDURES, BUT THERE IS NO SCIENTIFICALLY SURE WAY TO DO SO. FURTHERMORE, ESTIMATING THE RESPONSE TO THE LEVEL OF EXPOSURE USUALLY ENCOUNTERED IS MADE QUITE UNCERTAIN BY THE FACT THAT THE POTENTIAL ERROR IN THE RESPONSE GROWS AS THE DOSAGE IS LOWERED, DUE TO THE PRESENCE OF OTHER STRESSES ON THE TEST POPULATION THAT ARE UNKNOWN OR NOT ACCOUNTED FOR.

Inter-species extrapolation

Often, hazards potentially harmful to humans are discovered or are assessed in experiments on animals. The validity of extrapolating the dose-response relationship to humans is highly uncertain. Furthermore, different animal species respond differently. Yet, few people would advocate massive testing programs on humans to validate animal tests. Thus, estimates of the human response to hazards are often inherently uncertain.

Sensitive individuals and groups

The human population is highly variable in many respects. Susceptible subgroups such as pregnant women, children, asthmatics, the aged, or those previously exposed to other harmful substances are the ones society may be especially anxious to protect through regulation. The average dose-response relationship for the population as a whole fails to measure the health effects for these sub-populations, and thus provides an inadequate basis for policy analysis. However, very little data are available on the response of these groups to health hazards.

Risk estimates, unlike cost estimates, often involve different types of harm which cannot be appropriately reduced to a single measure; e.g., lung cancer deaths, disability from

INDUSTRIAL ACCIDENTS, AND HEARING LOSS. THEREFORE, COMPARISON OF DIFFERENT KINDS OF RISKS IS A DIFFICULT, VALUE-LADEN TASK.

ALSO UNLIKE COST ESTIMATES, RISK ESTIMATES ARE OFTEN SO UNCERTAIN THAT IT IS HIGHLY MISLEADING TO PRESENT THEM AS SINGLE POINT ESTIMATES--I.E., A SINGLE NUMBER SUCH AS THE NUMBER OF CANCERS. OFTEN, DECISION-MAKERS ARE CONFRONTED WITH HAZARDS WHICH MUST BE VIEWED AS COMPLEX PROBABILITY DISTRIBUTIONS RANGING OVER SEVERAL ORDERS OF MAGNITUDE. THIS HAS OCCURRED PARTICULARLY IN CASES WHICH HAVE BEEN THE SUBJECTS OF GREAT CONCERN; E.G., PCB'S, ASBESTOS, AND THE CHLORINATED HYDROCARBONS IN DRINKING WATER.

THE EVALUATION OF DIFFERENT RISKS AND DIFFERENT OPPORTUNITIES FOR RISK REDUCTION MUST TAKE INTO ACCOUNT A WIDE RANGE OF FACTORS IN ADDITION TO THE ABSOLUTE MAGNITUDE OF THE RISK. AMONG THE OTHER FACTORS RELEVANT TO THE SOCIAL VALUE JUDGEMENT IN INDIVIDUAL CASES ARE THE CHARACTERISTICS OF THE POPULATION AT RISK, E.G., WORKERS VERSUS CONSUMERS; WHETHER THOSE AT RISK ALSO RECEIVE THE BENEFITS OF A PARTICULAR TECHNOLOGICAL ACTIVITY; AND HOW THE POPULATION AT RISK PERCEIVES AND REACTS TO THE ASSUMPTION OF THAT RISK.

RISK MANAGEMENT INVOLVES COMPLEX DECISION-MAKING. DIFFERENT KINDS OF RISK ARE ADDRESSED BY DIFFERENT MANDATES WHICH HAVE ALREADY BEEN EXPRESSED IN VARIOUS ENVIRONMENTAL, HEALTH, AND SAFETY LEGISLATION. WHILE REGULATORY AGENCY PERFORMANCE

NEEDS IMPROVEMENT, CONGRESSIONAL SUPPORT FOR EXISTING LEGISLATION WOULD BRING ABOUT BETTER CHANGES THAN THOSE OFFERED IN H.R.4939.

THE LOCATION OF A CENTRALIZED ENTITY FOR PERFORMING COMPARATIVE RISK ASSESSMENTS WITHIN OSTP UNDERMINES THE BASIC CONSIDERATION THAT RISK MANAGEMENT DECISIONS ARE SOCIAL POLICY DECISIONS WHICH ARE BASED ONLY PARTLY ON HARD SCIENCE. ATTEMPTS TO SEPARATE THE SCIENTIFIC BASIS FOR THESE DECISIONS FROM OTHER CONSIDERATIONS RELEVANT TO SOCIAL POLICY DESIGN ARE AS MISGUIDED AS EARLIER ATTEMPTS TO ESTABLISH A SCIENCE COURT TO AID IN TECHNOLOGICAL DECISION-MAKING.

IN THE ENVIRONMENTAL, HEALTH, AND SAFETY AREA WE OFTEN PROTECT POPULATIONS FROM RISKS THAT ARE NOT ESTABLISHED WITH GREAT CERTAINTY OR UNEQUIVOCAL SCIENTIFIC VALIDITY. WE ALSO ACT TO GUARD AGAINST SMALL PROBABILITIES OF CATASTROPHIC EFFECTS. WE OFTEN DO THIS IN ORDER NOT TO REGRET WAITING FOR THE HARD DATA TO COME IN. THE FOOD, DRUG, AND COSMETICS ACT, THE OCCUPATIONAL SAFETY AND HEALTH ACT, THE CONSUMER PRODUCT SAFETY ACT, AND THE TOXIC SUBSTANCES CONTROL ACT ALL ENCOURAGE A RISK-AVERSE POSTURE ON THE PART OF AGENCIES IN PROTECTING THE PUBLIC.

THE DECISIONS OF THESE AGENCIES MUST GO FAR BEYOND HARD DATA. WE BELIEVE THAT SCIENTISTS ALONE, OR A SINGLE, EXECUTIVE BRANCH AGENCY LIKE OSTP NOT DIRECTLY ACCOUNTABLE FOR

REGULATORY POLICY TO CONGRESS OR THE PUBLIC, SHOULD NOT HEAVILY INFLUENCE RISK MANAGEMENT DECISIONS BY THE GOVERNMENT WHEN SUITABLE AND CONSTANTLY IMPROVING CAPABILITY EXISTS IN THE APPROPRIATE REGULATORY AGENCIES.

THE SEARCH FOR A TRULY APPROPRIATE SINGLE YARDSTICK FOR EXPRESSING DIFFERENT RISKS IS LIKELY TO CONTINUE TO BE DIFFICULT. THE VERY PROCESS OF TRYING TO EXPRESS DIFFERENT KINDS OF RISKS AND DIFFERENT KINDS OF BENEFITS FROM RISK REDUCTION WITH A COMMON MEASURE WILL TEND TO IGNORE AND OBSCURE DETAILS. THESE DETAILS MAY WELL BE OF CRITICAL IMPORTANCE FOR A TRULY REALISTIC COMPARATIVE ASSESSMENT OF THE DESIRABILITY OF DIFFERENT KINDS OF GOVERNMENTAL EFFORTS TO PROTECT THE PUBLIC.

FOR THESE REASONS WE BELIEVE THAT STRENGTHENING CONGRESSIONAL SUPPORT FOR ENVIRONMENTAL, HEALTH, AND SAFETY LEGISLATION BY INCREASING APPROPRIATIONS AND BY RESISTING ATTEMPTS TO WEAKEN THE REGULATORY MANDATES TO PROTECT THE PUBLIC FROM UNREASONABLE RISKS WILL RESULT IN A MORE SENSIBLE MANAGEMENT OF THOSE RISKS THAN THE APPROACH SUGGESTED IN H.R.4939.

ATTACHMENT B

American Journal of Industrial Medicine 3:241-242 (1982)

EDITORIAL

Risk Assessment and the Design of Policy for Worker Protection

The need for quantitative risk assessment has been thrust upon the scientific community. It will be a great challenge for scientists to respond to the increasing call for simple numbers. The scientific community must appropriately convey 1) the information available or deducible about particular risks, 2) the uncertainties in the quantitative information, and 3) unquantifiable but policy-relevant facts about the circumstances surrounding specific risks (e.g. "voluntariness" and "reversibility" of risk assumption, and the nature of the populations at risk.)

In a controversial and divided majority opinion following the first serious successful industy challenge of an OSHA standard on benzene in the Fifth Circuit Court of Appeals, the Supreme Court chided OSHA for not having made an attempt to evaluate the benefits of changing the permissible exposure level for benzene from 10 ppm (the old TLV) to 1 ppm. The Court was careful to say that it was not attempting to "statistically straitjacket" the agency, but rather that, at a minimum, the benefits of regulation needed to be addressed in order to provide the required "substantial evidence" that such regulation was necessary. The Court did not give useful guidance as to what constituted a significant risk. It stated that a risk of death in 1 in 10^3 was clearly unacceptable, while a risk of death of 1 in 10^6 might be tolerated. This 3-orders-of-magnitude range, of course, represents the area that the social policy arguments have always been centered on.

The risk from exposure to a specific level of toxin is rarely expressible as a single number, but is more correctly viewed as a probability distribution, or risk profile. For example, for a risk with a "best point-estimate" of 10^{-7}, there might be a five percent chance that the true level of risk might be 10^{-3} or 10^{-11}. In view of the health-protective mandate of the OSHAct, it is particularly necessary for OSHA, when considering standards for carcinogens, to take appropriate notice of the many types of circumstances which can lead to much greater human risks than might be inferred from simple "best estimate" calculations based on standard linear no-threshold interpolation. Among these circumstances are differences in species sensitivity, differences in individual sensitivity, and multiple exposure histories.

The construction of a risk profile for a real human cohort based on a neat dose-response relationship from animal experiments, or even from human epidemiology, is enormously difficult. From a social policy perspective, differing degrees of confidence (expressed in the shape and breadth of the risk profiles) might cause us to control two chemical exposures to different extents even if they had the same single point-estimates of likely harm.

Often, reliable dose-response data are available only for relatively high exposure levels. Interpolation of these data often suggest that significant health effects will occur at the lower doses typical of occupational or environmental exposure, but controversy exists over the proper mode of interpolation. Theoretical models have been proposed to support various interpolation procedures, but there is no scientifically accurate way to verify these. Furthermore, estimating the response to a given level of exposure is made quite uncertain by the fact that the potential error in response grows as the dosage is lowered, due to the possible presence of other stresses on the test population that are unknown or not taken into consideration. Even in the case where interpolation to lower doses from human exposure data is attempted, wide scientific disagreement occurs, as in the current controversy over the IARC report on benzene.

Often, hazards potentially harmful to humans are discovered or assessed in experiments performed on animals. Projection of results from animals to humans always introduces uncertainty, but these uncertainties should not be used as an excuse for ignoring potentially significant health problems. For example, the present OSHA administration seems reluctant to extend the discovery of the carcinogenic effects of formaldehyde in animals to humans. In doing so, OSHA may be ignoring an opportunity to prevent thousands of cancers (based on projections from animal studies) that otherwise might be prevented.

The human population is highly variable in many respects. Especially sensitive subgroups such as pregnant women, children, asthmatics, the aged, or those previously or concurrently exposed to other harmful substances are the ones society may be especially anxious to protect through regulation. The average dose-response relationship for the population as a whole fails to measure the health effects for these subpopulations, and thus provides an inadequate basis for policy analysis. Moreover, very few data are available on the response of these groups to health hazards.

All of these difficulties in risk assessment demonstrate the futility of using single numbers–or even simple distributions–in describing risk in a given exposed population. The decisions of whether or at what level to regulate health hazards is a social policy decision that can only partly rest on a formal risk assessment.

The implications of the Supreme Court decision on benzene for future standards will depend on the nature of the particular OSHA administration in power. There is little question that had OSHA performed a risk assessment for benzene it could have argued that the risk it was attempting to address was in fact significant. On the other hand, a lax administration could just as easily decline to declare the risk as significant, and leave the protection at the current level of 10 ppm. The precise requirement and nature of a risk assessment sufficient to meet the substantial evidence test on court review of OSHA's standards remains quite unclear. What is clear are the dangers of simplistic approaches to risk assessment which greatly understate the possible magnitude of a particular problem.

Nicholas A. Ashford, Ph.D., J.D.,
Assistant Director,
Associate Professor of Technology and Policy,
Center for Policy Alternatives,
M.I.T.,
Cambridge MA 02139

DeWet and J. M. Harlan, *Euphytica* **21**, 271 (1972); J. R. Harlan, *Crops and Man* (American Society of Agronomy, Madison, Wis., 1975); _____, J. M. J. DeWet, E. G. Price, *Evolution* **27**, 311 (1973); S. Miranda C. (or S. M. Colin), *Memorias del Segundo Congreso Nacional de Fitogenética, Monterrey, N.L., Mexico* (1966), p. 233.
26. G. N. Collins, *J. Agric. Res.* **17**, 127 (1919).
27. F. G. Brieger, *An. Esc. Super. Agric. "Luiz de Queiroz," Univ. São Paulo* **2**, 225 (1944); *Bragantia* **5**, 659 (1945).
28. P. C. Mangelsdorf, *Bot. Mus. Leafl. Harv. Univ.* **12**, 33 (1945).
29. H. G. Wilkes, *ibid.* **22**, 297 (1970); W. C. Galinat, *Mass. Agric. Exp. Stn. Bull.* 585 (1970).
30. P. Weatherwax, *The Story of the Maize Plant* (Univ. of Chicago Press, Chicago, 1923).
31. D. W. Galinat and W. C. Galinat, *Maize Genet. Coop. Newsl.* **46**, 109 (1972).
32. K. V. Flannery, *Annu. Rev. Anthropol.* **2**, 271 (1973).
33. J. H. Schaffner, *Bot. Gaz. (Chicago)* **84**, 440 (1927); *ibid.* **90**, 279 (1930); *Bull. Torrey Bot. Club* **62**, 387 (1935); J. Heslop-Harrison, *Proc. Linn. Soc. London* **172**, 108 (1961).
34. H. Iltis, *Sitzungsber. Akad. Wiss. Wien Math.-Naturwiss. Kl.* **Abt. 1 119**, 1 (1910).
35. _____, *Z. Indukt. Abstamm. Vererbungsl.* **5**, 38 (1911).
36. E. G. Montgomery, *Pop. Sci. Mon.* **68**, 55 (1906).
37. W. A. Kellerman, *Meehan's Mon.* **5**, 44, 53 (1895).
38. W. C. Galinat and A. W. Naylor, *Am. J. Bot.* **38**, 38 (1951).
39. P. Ascherson, *Sitzungsber. Bot. Vereins Prov. Brandenburg* **21**, 133 (1880).
40. J. H. Kempton, *J. Hered.* **14**, 242 (1923).
41. E. G. Montgomery, *Pop. Sci. Mon.* **79**, 346 (1911).
42. _____, *The Corn Crops* (Macmillan, New York, 1913).
43. E. M. East, *Pop. Sci. Mon.* **82**, 225 (1913); K. Goebel, *Biol. Zentralbl.* **30**, 692 (1910); G. N. Collins, *J. Wash. Acad. Sci.* **2**, 520 (1912).
44. P. C. Mangelsdorf and R. G. Reeves, *Tex. Agric. Exp. Stn. Bull.* 574 (1939).
45. E. Anderson, *Ann. Mo. Bot. Gard.* **31**, 325 (1944); _____ and W. L. Brown, *ibid.* **35**, 323 (1948).
46. W. C. Galinat, *Bot. Mus. Leafl. Harv. Univ.* **17**, 217 (1956); *Mass. Agric. Exp. Stn. Bull.* 577 (1969).
47. P. Weatherwax, *Bull. Torrey Bot. Club* **45**, 309 (1918); *Am. Midl. Nat.* **16**, 1 (1935).
48. L. F. Randolph, *Econ. Bot.* **30**, 321 (1976); in *Corn and Corn Improvement*, G. F. Sprague, Ed. (Academic Press, New York, 1955), p. 16; J. W. Harshberger, *Contrib. Bot. Lab. Univ. Pa.* **1**, 75 (1893).
49. P. C. Mangelsdorf and R. G. Reeves, *Am. Anthropol.* **47**, 235 (1945).
50. H. G. Wilkes, *Teosinte: The Closest Relative of Maize* (Bussey Institute, Harvard University, Cambridge, Mass., 1967).
51. M. Lenehan, *The Reader (Chicago)*, 26 September 1975.
52. J. W. Harshberger, *Gard. For.* **9**, 522 (1896).
53. A. Gustafsson, *Evolution* **5**, 181 (1951).
54. In 1906, Montgomery (*36*) derived maize and teosinte from a perfect-flowered common ancestor. In 1911 (*41*, p. 347), he suggested "that the ear was a development from the central spike of the tassel borne on a lateral branch of the [maize?] plant, the other branches of this tassel becoming abortive." In 1913, he finally derived maize from teosinte (*42*, p. 18): "in this evolution the central spike of the [teosinte] tassel developed into an ear [of maize]" and went on to state that, in teosinte, "the terminal tassel-like structure . . . borne in a leaf axil, surrounded by a kind of husk as is an ear of maize, and [bearing] only pistillate flowers . . . is only a step in the production of an ear of maize, from teosinte, by a development of the central spike of the lateral [teosinte] tassel into [a maize] ear." Lacking the clarity needed to convince his peers, Montgomery's 1913 text has rarely been cited (*30*) and never evaluated. While Wilkes (*50*) lists the 1920 revised edition of *The Corn Crops* in his bibliography [which, in the quoted passages, is identical to the 1913 edition (*42*)], neither Montgomery nor his ideas are discussed.
55. G. Torres B. (or G. T. Barusta) *Agricultura (Mexico)* **1**, 3 (1938).
56. P. C. Mangelsdorf, *Adv. Genet.* **1**, 161 (1947).
57. J. S. Rogers, *Genetics* **35**, 541 (1950).
58. L. F. Randolph, *Maize Genet. Coop. Newsl.* **46**, 8 (1972).
59. D. G. Langham, *Genetics* **25**, 88 (1940).
60. Of all postulated genes, only for alleles at the dominant *Tu* (tunicate) locus (podcorn, an atavistic abnormality of no significance to this controversy) is there evidence of monogenic inheritance.
61. M. K. Chailakhyan and V. N. Khryanin, in *Plant Growth Substances*, F. Skoog, Ed. (Springer-Verlag, Berlin, 1980), p. 331.
62. F. D. Richey and G. F. Sprague, *Am. Nat.* **66**, 433 (1932).
63. N. H. Nickersen, *Ann. Mo. Bot. Gard.* **47**, 243 (1960); S. B. Rood, R. P. Pharis, D. J. Major, *Plant Physiol.* **61**, 793 (1980); G. K. Molotkovskii, *Dokl. Bot. Sci.* **175**, 238 (1967).
64. F. Skoog, Ed., *Plant Growth Substances* (Springer-Verlag, Berlin, 1980).
65. J. F. Doebley, personal communication.
66. Crowding of annual teosinte results in the deletion of the primary branch axes, especially the lower and middle ones, to provide monopodial unbranched plants. Such deletion is an either-or threshold phenomenon quite different from reduction in branch internode length (condensation) discussed here. Despite claims to the contrary (*21*, *31*), neither teosinte ear clustering nor primary branch deletion were involved in the early evolution of maize.
67. P. Weatherwax, in *Corn and Corn Improvement*, G. F. Sprague, Ed. (Academic Press, New York, 1955), p. 89.
68. J. L. Harper, *Population Biology of Plants* (Academic Press, London, 1977).
69. C. Johanneson, personal communication.
70. P. C. Mangelsdorf, *Proc. Am. Philos. Soc.* **102**, 454 (1958).
71. E. Mayr, *Populations, Species, and Evolution* (Belknap, Cambridge, Mass., 1970).
72. C. H. Waddington, *The Strategy of the Genes* (Allen & Unwin, London, 1957).
73. G. L. Stebbins, Jr., *Variation and Evolution in Plants* (Columbia Univ. Press, New York, 1950).
74. J. F. Doebley, M. M. Goodman, C. W. Stuber, *Syst. Bot.*, in press.
75. M.-C. King and A. C. Wilson, *Science* **188**, 107 (1975).
76. See K. Schumann, in *Festschrift für P. Ascherson*, I. Urban and P. Graebner, Eds. (Borntraeger, Leipzig, 1904), p. 137; P. Weatherwax and L. F. Randolph, in *Corn and Corn Improvement*, G. F. Sprague, Ed. (Academic Press, New York, 1955), p. 10; G. N. Collins, *Bull. Torrey Bot. Club* **57**, 199 (1930); H. C. Cutler, *Bot. Mus. Leafl. Harv. Univ.* **12**, 257 (1946).
77. H. H. Iltis, *Ann. Mo. Bot. Gard.* **44**, 77 (1957).
78. E. Mayr, *Animal Species and Evolution* (Belknap, Cambridge, Mass., 1963).
79. With their often cone-like gynoecia, early angiospermous flowers could well have evolved from loosely structured branch systems adapted to wind pollination which telescoped into the tightly focused reproductive efforts that animal-pollinated flowers represent and demand.
80. S. J. Gould, *The Panda's Thumb* (Norton, New York, 1980).
81. W. H. Wagner, personal communication.

ATTACHMENT C

82. I give special thanks to G. W. Beadle for inviting me to participate in the 1971 NSF-supported Mexican "teosinte mutation hunt"; J. F. Doebley and T. F. H. Allen for both enthusiastic criticism and support; J. H. Loonquist for growing the indispensable maize × teosinte hybrids; B. F. Benz, J. S. Denslow, D. N. Duvick, W. C. Galinat, T. R. Soderstrom, D. M. Waller, H. G. Wilkes, and S. Wright for helpful comments; L. C. Taylor for aid with illustrations; and especially D. A. Kolterman for help with the manuscript. Supported by NSF grants BMS 74-21861 and DEB 80-22772; Pioneer Hi-bred International, Inc., Johnston, Iowa; and the E. K. and O. N. Allen Herbarium Fund, University of Wisconsin–Madison.

Law and Science Policy in Federal Regulation of Formaldehyde

Nicholas A. Ashford, C. William Ryan, Charles C. Caldart

Formaldehyde, one of the more widely used chemicals in modern industry, has recently become one of the more controversial as well. A plethora of lawsuits, congressional hearings, and scholarly analyses have centered on formaldehyde, and more particularly on federal agency responses to new data indicating that it may be a carcinogen. These developments were sparked by an October 1979 report from the Chemical Industry Institute of Toxicology (CIIT) that formaldehyde causes cancer in rats.

On receiving the CIIT findings, the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the Consumer Product Safety Commission (CPSC), and other agencies undertook several joint actions, the most important of which was to form the Federal Panel on Formaldehyde. The panel was composed of top scientists from the federal government and was directed to evaluate all available information on the long-term effects of exposure to formaldehyde and to assess the human health risks. In November 1980 the panel pesented its report to the agencies. Based on its review of the available data, the panel concluded that "formaldehyde should be presumed to pose a carcinogenic risk to humans" (*1*). Thereafter, CPSC issued a ban against the use of urea-formaldehyde foam insulation. EPA and OSHA, however, declined to take regulatory action against formaldehyde.

Nicholas A. Ashford is associate professor of technology and policy and director of the Center for Policy Alternatives, Massachusetts Institute of Technology, Cambridge 02139. C. William Ryan is on the research staff and Charles C. Caldart is a staff attorney at the Center for Policy Alternatives.

Summary. An examination of the way in which the Environmental Protection Agency, Occupational Safety and Health Administration, and Consumer Product Safety Commission each responded to evidence of formaldehyde's carcinogenicity in animal systems reveals the interplay between politics and science policy in regulatory determinations. In some cases there were significant and unjustified departures from reasoned decision-making. Agency decisions not to take action deserve special attention by citizens, the Congress, and the judiciary to ensure that federal regulatory agencies take the necessary steps to protect the public from significant health, safety, and environmental risks.

Framework for Evaluating the Formaldehyde Decisions

The great weight of judicial authority suggests that the appropriate legal standard by which to evaluate agency decisions is whether the agency engaged in "reasoned decision-making" (*2*). As recently articulated by the D.C. Circuit Court (*3*), an agency practices reasoned decision-making when it (i) takes a "hard look . . . at the relevant issues," (ii) deliberates "in a manner calculated to negate the danger of arbitrariness and irrationality," (iii) violates "no law," and (iv) provides an "articulated justification" that makes a "rational connection between the facts found and the choice made."

Applying the concepts of reasoned decision-making as an analytical tool requires a clear understanding of what a particular agency has and has not done. With health risk determinations, this understanding often requires a technical knowledge of the underlying data and methodologies. Further, it requires an ability to distinguish between purely technical determinations and those based on the more subjective, science policy determinations.

The term "science policy" denotes issues that are grounded in scientific analysis but for which technical data are insufficient to support an unequivocal scientific conclusion. The ultimate resolution of these issues depends on determinations of social policy. Distinguishing science policy determinations from those of a truly technical nature is a central step in evaluating the adequacy of an agency's assessment of human health risks. Simply deferring to agency expertise on all determinations that appear to be "scientific" overlooks the subjective determinations at the heart of the agency's decisions. Such an approach frustrates any effort to measure agency decisions against the standard of reasoned decision-making.

Acknowledging that science policy will often play a major role in agency assessments of human health risks, it must then be determined whether an agency has abided by the principles of reasoned decision-making. These principles impose three primary responsibilities on an agency assessing health risks: (i) it must adequately evaluate the technical data, (ii) it must follow proper administrative procedures, and (iii) it must correctly carry out its statutory mandate. In practice, these functions overlap. An agency's interpretation of its statutory mandate, for example, can influence both the nature of the technical data it examines and the manner in which it makes that examination. When completed agency decisions are analyzed, however, the three elements are separable and provide a logical framework.

Treatment of technical data. In evaluating the technical data relevant to determining health risk, an agency must delve deeply into scientific issues. The agency will ordinarily engage in two levels of scientific analysis. On one level, it will address "hard" scientific issues that can be resolved with currently available methodologies. On a second level, the agency will confront various science policy issues that cannot be answered solely on a technical basis. Thus a meaningful critique of an agency's treatment of technical data requires both an understanding of the relevant technical methodology and an ability to distinguish between "hard" science and science policy determinations.

In appropriate circumstances, of course, the agency may depart from scientific opinion on science policy issues. These issues do, after all, involve policy determinations, and accordingly should be made by the governmental entity charged with reflecting the will of the people through the execution of a congressional mandate. Nonetheless, they are also determinations that should be properly based on a sufficient understanding of the underlying scientific evidence. When a majority position on a science policy issue has evolved within the scientific community, we believe the agency should not depart from that position without acknowledging and justifying the departure.

Adherence to procedural requirements. Science policy issues may also arise in the context of procedural matters. Agencies often develop general policy guidelines for their regulatory actions, in the form of either formal generic standards, such as OSHA's, or informal statements of procedure, such as the Regulatory Council's. These guidelines not only promote regulatory continuity but also provide notice to affected industries and interested members of the general public. As a matter of administrative procedure, an agency must adhere to its policy guidelines or identify and explain any change in, or departure from, those guidelines. To develop policy guidelines in the area of health risk assessment, the agency must adopt positions on science policy issues. In the absence of formal announcements of changes in these positions, recognizing policy departures will require that one first identify and understand the underlying science policy issues.

Execution of statutory mandates. Finally, the agency must act in accordance with its statutory mandate. This responsibility has two elements. The agency must carry out the specific duties of the particular statutory provisions under which it is considering regulatory action. At the same time, it must faithfully adhere to the more general aspects of the congressional mandate underlying its enabling legislation.

Any analysis of agency decision-making must carefully consider both of these elements. In evaluating health risk determinations, particular attention must be given to the ways in which assessments of science policy issues reflect an agency's interpretation of its statutory mandate. In close cases, for example, should the agency tip the balance in favor of finding a human health risk or in favor of deferring such a finding until additional data are available?

In developing a general analytical framework, we are not unmindful of the judicial deference traditionally afforded agency decisions not to act. In the past, legal challenges to agency decisions on health and safety have come primarily in response to specific regulatory actions. An agency's implementation of a statutory provision was challenged as either too zealous or insufficiently protective. In the present antiregulatory climate, challenges to agency decisions not to act may assume greater significance

Judicial deference to agency discretion in such situations is based largely on respect for agency expertise in matters of resource allocation and technical evaluation. Such deference is misplaced, however, where the cloak of expertise serves to disguise inadequate technical analysis, improper decision-making procedures, or statutory misinterpretation. An analysis of the formaldehyde decisions demonstrates why, before deferring to an agency's decision not to take regulatory action to protect human health, the courts should first study the agency's decision to determine whether such deference is, in fact, warranted.

EPA's Decision Not to Designate Formaldehyde a Section 4(f) Chemical

In March 1981 EPA's deputy assistant administrator for toxic substances, in consultation with other EPA officials, concluded that the agency was obligated to begin consideration of formaldehyde under section 4(f) of the Toxic Substances Control Act. Section 4(f) provides that once EPA receives information indicating that there "may be a reasonable basis to conclude" that a chemical poses a significant cancer risk, the agency has 180 days to either "initiate appropriate regulatory action" or publish an explanation of why the risk "is not unreasonable" (*4*).

When newly confirmed EPA administrator Anne Gorsuch assumed office in May 1981 she delayed action on formaldehyde pending additional review. Finally, on 10 February 1982, EPA released a memorandum, written by new assistant administrator John Todhunter, that analyzed the available evidence on formaldehyde carcinogenicity and exposure and concluded that section 4(f) had not been triggered.

In a sense, any discussion of EPA's decision-making process may be superfluous. Considerable evidence suggests that the incoming EPA officials had determined their policy on formaldehyde long before any "decision-making process" had been completed (*5, 6*). Assuming, however, that the Todhunter memorandum does represent the culmination of a lengthy decision-making process, this process was nonetheless flawed in numerous respects.

Analysis of technical data. An agency decision must evidence a "rational connection between the facts found and the choice made" (*3*). Health risk assessments thus require a careful analysis of the relevant technical data regarding both a substance's toxicity and the extent of human exposure. Unquestionably, an agency is properly accorded some discretion in its treatment of technical data. Nonetheless, the agency's analysis must be free of overt errors in technical methodology or reasoning. EPA's treatment of the formaldehyde data aroused significant criticism. A review of the agency's technical analysis reveals several examples of questionable scientific reasoning.

The Todhunter memorandum appears to contain significant lapses in hard science. In many cases it seems simply to ignore empirical data contrary to EPA's conclusions, or to rely on controversial factual assumptions without offering evidence in support of these assumptions. As has been discussed elsewhere (*7*), the questionable aspects of Todhunter's technical analysis include his reliance on methodologically inadequate epidemiologic studies, his presumption of site specificity and species specificity for formaldehyde carcinogenicity, his argument that the irritant properties of formaldehyde are the basis of its carcinogenicity, his assumption that humans will avoid formaldehyde exposures above 2 ppm, and his conclusion that formaldehyde exposure levels in homes with urea-formaldehyde foam insulation are no higher than those in other homes.

In his reliance on the epidemiologic studies and his assumption of site and species specificity, Todhunter also departed from the science policy conclusions of a scientific panel convened by the Interagency Regulatory Liaison Group (IRLG). Indeed, EPA's formaldehyde deliberations reflected science policy positions that represent the views of a minority in the scientific community (*7*). While these positions may not be "wrong" in a purely technical sense, they demand justification. EPA neither acknowledged the need for such justification nor supplied any.

Procedural aspects. The principle of reasoned decision-making further requires that an agency deliberate "in a manner calculated to negate the dangers of arbitrariness and irrationality" (*3*). Depending on the particular agency action under review, courts have enumerated various specific procedural requirements for reasoned decision-making. EPA's treatment of formaldehyde raises procedural questions.

Several of these questions concern a possible bias of EPA with respect to industry. With the advent of the Gorsuch administration, EPA embarked on a decision-making process for formaldehyde that served to maximize input from the formaldehyde industry and to minimize input from other sectors. Regardless of the ultimate substantive validity of the agency's section 4(f) determination, the appearance of its decision-making process lends credence to claims of impropriety.

The EPA held three meetings with representatives of the formaldehyde industry in summer 1981. The initial impetus for the meetings apparently came from industry. Although EPA has subsequently characterized these meetings as having been "exclusively scientific in nature," the rosters of those present reveal that the sessions were dominated by the perspective of the formaldehyde industry. With the exception of one or two "neutral" scientists at each meeting, the Formaldehyde Institute selected all the non-EPA participants.

Rather than solicit a variety of viewpoints, EPA closed the meetings to the public. Conspicuous by their absence were scientists representing groups that might be expected to oppose the formaldehyde industry's position. Also absent were representatives of other regulatory agencies and the IRLG. Indeed, the agency reportedly refused to admit two scientists who requested permission to attend: Andrew Ulsamer of CPSC and Han Kang of OSHA, both members of the IRLG formaldehyde group.

As other observers have suggested, these meetings may also have violated the Federal Advisory Committee Act (FACA) (*8*). That statute recognizes that agencies have come to rely on technical "advisory committees" as an aid to decision-making, and establishes specific procedural requirements for such committees. The Act requires that advisory committees be formally chartered, be composed of a "fair balance" among opposing viewpoints, give notice of their meetings and open them to the public, and maintain accurate and detailed minutes of those meetings.

The deputy administrator of EPA, John Hernandez, has written that the primary function of those sessions was to allow him to meet with "scientific and technical experts" to "discuss the scientific merits of the available information." The meetings, he indicated, "were designed . . . to explore fully the scientific and technical issues." He later testified that the purpose of the meetings was to "get all the scientific information pertaining to the exposure and toxicity of these substances out in the open." If this characterization is accurate, the meetings would probably fall within FACA's purview. EPA departed from the Act's procedural requirements in numerous particulars. Certainly, the narrow range of viewpoints represented at the industry meetings is inconsistent with the "fair balance" requirement of the Act.

A substantial amount of evidence indicates that before releasing his 10 February memorandum, Todhunter met on several occasions with John Byington, attorney for the Formaldehyde Institute, and Len Guarraia, then a director of the American Industrial Health Council and director for government relations for the Synthetic Organic Chemical Manufacturer's Association. Although the precise nature and scope of these gatherings are difficult to deduce, it seems that Todhunter did meet with formaldehyde interests before drafting EPA's position paper on the section 4(f) determination. As the D.C. Circuit Court has noted, "[t]he inconsistency of the *ex parte* contacts with reasoned decision-making and fairness to the public has been increasingly recognized in recent years" (*9*).

Shortly after they took office the new EPA administrators ceased to cooperate with the other federal agencies that were assessing formaldehyde carcinogenicity. EPA also isolated itself from its own science advisory board. On 29 October 1981 the board's executive committee recommended that EPA submit the formaldehyde issue to the National Academy of Sciences before it concluded its section 4(f) determination. EPA instead permitted Todhunter to draft his technical memorandum on formaldehyde without such assistance.

Other procedural questions concern the explanation given by EPA for its decision on formaldehyde. The courts have long required agencies to "articulate with reasonable clarity their reasons for a decision" (*2*). In the words of an oft-cited opinion (*10*), "the orderly functioning of the process of review requires that the grounds upon which the administrative agency acted be clearly disclosed and adequately sustained." EPA's formaldehyde deliberations fell far short of this standard.

The most troublesome procedural problem lies in Todhunter's failure to acknowledge his departure from prior agency positions on many of the science policy issues involved. Where an agency has changed a previously articulated policy or departed from a relevant agency precedent, the courts have required the agency to provide a detailed rationale. Although EPA never promulgated a formal cancer policy, it published informal cancer guidelines in 1976, endorsed the IRLG risk assessment document in 1979, and participated in the Regulatory Council's September 1979 policy statement on regulation of chemical carcinogens (*11*). Being most recent, the Regulatory Council's statement was the logical foundation for EPA's approach to formaldehyde, yet Todhunter's positions differ from the council's in several areas.

The guidelines specify that (i) negative epidemiologic studies will not be presumed to indicate that a substance is not carcinogenic, (ii) sites exposed by routes other than those tested will be presumed to be at risk, (iii) negative bioassay results for some animal species, even in well-conducted tests, will not be said to detract from well-established positive evidence for other species, and (iv) a no-effect threshold level will not be assumed to exist for carcinogenic substances. Todhunter adopted a contrary position on each of these points.

Todhunter also suggested that positive data on more than one species at more than one dose level should be a prerequisite to a determination of human risk. The Regulatory Council's guidelines require only positive data in a single species at one dose level. Similarly, Todhunter discounted findings of benign tumors in bioassay data and considered only verifiably malignant tumors, while the council concluded that benign tumors should be considered evidence of potential malignancy. The council statement also indicates that agencies will attempt to estimate the maximum risk that could reasonably be expected. Todhunter consistently assumed policy positions that minimized estimated risks. In its failure to explain or even acknowledge these policy reversals, EPA fell short of its procedural responsibility.

Finally, Todhunter's memorandum was not reviewed by his scientific peers inside or outside the agency. The failure to garner peer review, especially on matters so controversial, ran counter to the professed goal of the new EPA administrators to improve the scientific basis of the agency's regulatory decisions. It may also have violated internal EPA procedures. In January 1982 EPA implemented a new internal policy governing the review of scientific, informational, and educational materials. The policy, which applies to "any material prepared for distribution to anyone outside the agency," requires that at least two specialists review all such materials (*12*). Nonetheless, the Todhunter memorandum was released to the public without prior peer review.

Statutory mandate. Congress designed section 4(f) as a mechanism for early identification and regulation of those chemicals that were of particular concern because they are likely carcinogens, mutagens, or teratogens. EPA's current interpretation of that section, however, will frustrate this scheme.

As noted, section 4(f) requires agency action if there "may be a reasonable basis" to conclude that a risk of harm exists. In both common usage and judicial interpretation, "may" indicates the possibility of occurrence. Under the plain language of section 4(f), then, EPA cannot delay its threshold determination until a risk has become certain or probable, but rather must take action on learning of a credible possibility of such risk.

Todhunter's memorandum is particularly noteworthy in this respect. In summarizing the formaldehyde data, Todhunter noted that "there may be human exposure situations . . . which may not present carcinogenic risk which is of significance." He thus stated the required statutory finding in the negative. The logical converse of this statement—that there may be human exposure situations that do present significant carcinogenic risk—is precisely the finding that requires EPA to proceed under section 4(f). The agency's failure to do so reflects misinterpretation of statutory language.

The agency's assessment of the kind of risk that it is to consider under section 4(f) may also be inaccurate. Once again, the statute itself provides relatively clear guidelines. Congress dealt with both short-term and long-term risk in 4(f), which addresses chemical substances that either "present" or "will present" a significant risk of harm. The Toxic Substances Control Act does not define the phrase "significant risk," but the context suggests that "significance" pertains to the likelihood of occurrence. By providing that the risk that may exist must be significant, the Act seems to require only the possibility of a probable occurrence. Evidence indicating the possibility of a significant risk thus triggers the threshold determination that compels EPA to assess the risk more precisely.

In its risk assessment, the agency must consider both "serious" and "widespread" harm. By specifically distinguishing between these two categories of harm in section 4(f), Congress clearly indicated that either one will trigger a threshold determination. One element focuses on the extent to which the chemical may pose a risk of serious harm. Here the concern is not so much the number of people who may be affected, but how severely they may be affected. A low incidence of a debilitating cancer, then, would suffice. The other element is the extent to which the chemical may pose a risk of widespread harm. Here a higher incidence is required, but the harm need not be as severe.

After making a threshold determination of possible significant risk EPA must decide, within a prescribed time period, whether regulatory action is appropriate. If the agency determines that the risk is not unreasonable, it must subject this finding to public scrutiny by publishing it in the *Federal Register*. If, on the other hand, the agency does not conclude that the potential risk is not unreasonable, it must "initiate appropriate action . . . to prevent or reduce to a sufficient extent such risk." While we express no opinion here as to the appropriate regulatory response to formaldehyde under the Toxic Substances Control Act, it appears that section 4(f) requires something more of EPA than the agency's actions to date.

OSHA's Decision Not to Issue an Emergency Temporary Standard

After receiving the results of the preliminary CIIT bioassay in late 1979, both OSHA and the National Institute for Occupational Safety and Health began preparing a joint current intelligence bulletin (CIB) on formaldehyde. A pre-publication version was made available to the public in December 1980. The CIB recommended that "formaldehyde be handled as a potential occupational carcinogen and that appropriate controls be used to reduce worker exposure."

In March 1981 Thorne Auchter assumed office as assistant secretary of labor for OSHA. Soon thereafter he withdrew OSHA's sponsorship of the CIB.

In October 1981 the United Auto Workers and 13 other major labor unions petitioned OSHA to set an emergency temporary standard (ETS) for formaldehyde under section 6(c) of the Occupational Safety and Health Act (*13*). Section 6(c) specifies that OSHA shall promulgate an ETS if it determines that employees are exposed to "grave danger" from exposure to a hazard and that an ETS is "necessary to protect employees from such danger." In a letter dated 29 January 1982, Auchter denied the petition. He stated that OSHA assessments indicated that risks at the current permissible exposure level of 3 ppm were not sufficient to warrant a finding of grave danger, and that current employee exposure levels were below 3 ppm.

Auchter's decision to deny the union's ETS petition was apparently based on two evaluations performed by agency personnel after Auchter took office. The first is a review of a formaldehyde risk assessment prepared by scientists at the Massachusetts Institute of Technology, and the second, the agency's preliminary risk assessment. Positions expressed in each of these documents found their way into Auchter's ultimate statement of rationale, although the extent to which they contributed to the ETS decision is not altogether clear.

In many ways, OSHA's deliberations on formaldehyde mirrored EPA's. Although OSHA's departures from sound technical reasoning and established administrative procedure were perhaps less troublesome than EPA's, they were nonetheless significant. OSHA's treatment of science policy issues provides an excellent example of how such issues can cut across all three levels of an agency's administrative responsibility.

Analysis of technical data. The review of the MIT study inappropriately relies on the formaldehyde epidemiologic studies, on arguments of species specificity, and on arguments of minimum exposure. The review also assumes that workers are exposed only to low levels of formaldehyde, avoiding exposures above 3 ppm because of their irritating effects. Like the Todhunter memorandum, the OSHA review cites no empirical evidence for this assumption and apparently ignores data on exposures above the 3 ppm level.

Furthermore, the review departs from prevailing scientific opinion on science policy. As previously noted, the review presumes species specificity and relies on negative epidemiologic data. In an even more striking departure, the review does not merely question the way results of animal bioassays are extrapolated to humans, but rather argues that such extrapolation is meaningless: "Because of the vast uncertainties in extrapolating from experimental rodent studies to man, such experiments do not and cannot predict or measure human risks." At best, this sweeping denunciation of accepted science policy represents a controversial minority opinion.

Procedural aspects. Perhaps the most significant procedural deficiency in OSHA's deliberations was the agency's failure to adhere to its own policy on cancer risk assessment. Although that policy was promulgated as a formal agency regulation, which is still in effect, Auchter's denial letter does not acknowledge it. Indeed, Auchter's treatment of the rat data and the agency's failure to consider benign tumor data conflict with the policy's plain language. The OSHA review of the MIT report also departs significantly from the agency's cancer policy, again without acknowledging or explaining the departure.

Although the Auchter letter contains a statement of rationale, that statement does not identify the agency "risk assessments" on which it says it relies. Does it refer only to the OSHA assessment made after the ETS petition was filed, or does it refer also to the agency's earlier review of the MIT study? Indeed, the OSHA assessment appears to have been prepared in written form sometime after Auchter's letter was delivered to the unions. This fact, along with the conclusory nature of Auchter's analysis, calls into question the letter's adequacy as a "statement of reasons." The possibility of post hoc rationalization looms large here.

A final procedural problem with OSHA's formaldehyde deliberations is that the agency disregarded and mischaracterized the advice of its own scientists. Although Auchter publicly stated that the agency withdrew its support of the formaldehyde CIB because it "lacked confidence in the data" on which the CIB was predicated, all the technical personnel in OSHA's carcinogenicity assessment group supported both the CIB and the underlying data. Later, when Peter Infante, director of OSHA's Office of Carcinogen Identification and Classification, wrote to the International Agency for Research on Cancer (IARC) recommending that formaldehyde be classified as an animal carcinogen, the agency took steps to have him dismissed. The matter became the focus of a congressional hearing. Subsequently, the dismissal proceedings were canceled.

Statutory mandate. The issuance of an ETS for a workplace chemical under section 6(c) depends on a finding that "employees are exposed to grave danger from exposure" to that chemical. A review of OSHA's formaldehyde decision indicates that the agency may have adopted a more limited interpretation of section 6(c) than the statute will permit.

Clearly, cancer is a "grave" illness. The question is what degree of cancer risk constitutes a "grave danger" under section 6(c). The Third Circuit Court provided guidance in a 1973 opinion (*14*), stating that "[w]hile the Act does not require an absolute certainty as to the deleterious effect of the substance on man, an emergency temporary standard must be supported by evidence that shows *more than some possibility* that a substance may cause cancer in man" [italics added].

A review of OSHA records shows that such evidence was available during the formaldehyde deliberations. Extrapolating from the CIIT rat bioassay results, the agency's own risk analysis indicates that four formaldehyde-related cancer deaths per 1000 exposed workers would be expected at the currently permitted exposure level of 3 ppm. Because OSHA estimated that the average occupational mortality rate for manufacturing workers, from all reported occupationally related causes, is also four per thousand, Auchter concluded that formaldehyde does not pose a grave risk of danger. This comparison misses the mark. The question is not how the risk from formaldehyde compares with the aggregate of all other risks, but how many lives can be saved by regulating formaldehyde exposure. Furthermore, if the agency's estimate of average aggregate risk is valid, the fact that exposure to formaldehyde alone presents a risk of comparable magnitude should give rise to considerable concern.

This evidence of carcinogenic potency appears sufficient to warrant the issuance of an ETS, assuming that a determination of "grave danger" under section 6(c) may be made by extrapolating from animal data. Dicta from the Third Circuit Court again provide substantial guidance (*13*): "Extrapolation from animal experiments may in appropriate cases be used to establish a sufficient probability of harm to man." Moreover, the courts have indicated that evidence of animal carcinogenicity is by itself sufficient to justify a permanent standard. A greater burden would hardly seem appropriate for a temporary standard. In addition to contravening its own cancer policy and the IRLG guidelines on this issue, OSHA contravened its section 6(c) mandate as well.

The remaining inquiry is whether the evidence of worker exposure to formaldehyde is sufficient to warrant issuing an ETS. In a recent decision involving ethylene oxide, the D.C. Circuit Court declined to compel OSHA to issue an ETS where the evidence indicated that only "some" workers are exposed to ethylene oxide at levels that present a "significant risk" of "grave danger." On the basis of this finding, however, the court ordered OSHA to expedite ongoing procedures to set a permanent standard to reduce worker exposure to ethylene oxide. The data on formaldehyde exposure appear to be stronger than the data on ethylene oxide, both in the detail and reliability of the exposure information and in the number of workers exposed. Indeed, the D.C. Circuit's approach in the case of ethylene oxide may also be appropriate for formaldehyde. An order to commence a procedure to set a permanent standard for formaldehyde would set the stage for an objective appraisal of the cancer risk and of the need for further worker protection.

CPSC's Decision to Ban Urea-Formaldehyde Foam Insulation

The Consumer Product Safety Commission received the results of the preliminary CIIT bioassay in late 1979. By this time, the commission had already begun to study the health problems associated with the use of urea-formaldehyde foam insulation (UFFI). In March 1980, when the need for further study became apparent, CPSC organized the Federal Panel on Formaldehyde. In June 1980 CPSC proposed a rule requiring UFFI manufacturers to inform prospective buyers of UFFI health effects. The commission received the panel report in November 1980, and in February 1981 it proposed to ban UFFI altogether. Ultimately it promulgated a final rule banning UFFI as of August 1982.

On 12 April 1982 the Formaldehyde Institute filed a suit to challenge the CPSC ban. On 10 August of that year a federal judge refused to issue a temporary injunction, and the ban took effect on that date. The Fifth Circuit Court vacated the UFFI ban on 7 April 1983 and has recently reaffirmed its decision.

Especially when viewed in contrast to the EPA and OSHA deliberations, CPSC's formaldehyde deliberations might be considered a model of reasoned decision-making. The commission was subject to more stringent statutory requirements than were EPA and OSHA. However, it not only met these requirements, but exceeded them.

Analysis of technical data. During the notice and comment rule-making period for the UFFI ban, CPSC responded to many comments that specifically questioned its technical risk analysis. A search of the commission's stated rationale, background documents, and comment responses reveals no clear errors in scientific reasoning.

The commission conformed to prevailing scientific opinion on science policy issues. For example, it extrapolated animal results to humans and high-dose results to low doses.

Procedural aspects. In promulgating its UFFI ban, CPSC was subject to the procedural provisions of the Consumer Product Safety Act, which require an opportunity for notice and comment. In addition, as a commission headed by a "collegial body," CPSC must comply with advance notice and open meeting requirements of the government in the Sunshine Act. CPSC appears to have conformed to these requirements and to have comported with the principles of reasoned decision-making. It established and maintained a decision-making framework that allowed for input from all interested parties.

The commission's UFFI science policy decisions were consistent with the Regulatory Council's policy on the regulation of carcinogens, which CPSC explicitly endorsed. The commission also provided a detailed statement of reasons for its decision to ban UFFI. That statement explains the basis of the ban, cites specific sources of data, and responds to numerous comments.

The Fifth Circuit Court Opinion Overturning the UFFI Ban

The Fifth Circuit Court does not share our sanguinity regarding the CPSC cancer risk assessment. The court criticized two aspects of the commission's risk assessment: the manner in which homes were selected for measurements of in-home formaldehyde levels and the use of the CIIT data on rats to project human carcinogenic risk. The court indicated that CPSC's handling of either of these factors would be sufficient to warrant reversal of the UFFI ban. We disagree.

The CPSC based its estimate of likely formaldehyde exposure levels on 1164 measurements from homes insulated with UFFI and on laboratory tests on UFFI panels. Of the in-home measurements, 827 were conducted in residences whose occupants had complained about UFFI-related health problems and 337 in homes selected for other reasons. In concluding that these in-home measurements were an improper basis for the commission's risk assessment, the court points to two "significant omissions" (*15*):

> The Commission does not explain its reliance on a data base comprised largely of complainant houses. Nor does the agency justify its failure to conduct a study of randomly selected UFFI homes before issuing the product ban.

In truth, however, the agency did explain its willingness to rely on the in-home data. According to the final risk assessment, all the in-home measurements (for both "complaint" and "noncomplaint" homes) were grouped according to the time that had elapsed between the date that UFFI had been installed and the date that the measurement had been taken. The groupings were by 10-week periods over a period of 9 years. Average measurements for complaint homes were compared with average measurements for noncomplaint homes within each of these 10-week periods, but no statistically significant differences were found. Thus, the agency concluded, there is no reason to believe that formaldehyde levels in the complaint homes were significantly higher than those in other homes insulated with UFFI. While the statistical comparison employed by the agency does not rule out the possibility that use of complaint homes did influence the data to a certain degree, the data indicate that the effect of any such influence on the ultimate cancer risk projection would be relatively small.

The failure to use a randomized sample is perhaps a closer question. Although selecting a study population through random sampling would be scientifically preferred, failing to do so does not necessarily vitiate the value of a study. The obvious source of potential bias in the CPSC data—and the only one cited by the court—is the possibility that formaldehyde levels were appreciably higher in the complaint homes than in other homes. As noted, however, comparisons between complaint and noncomplaint homes revealed no statistically significant differences in formaldehyde levels.

There remains a possibility that the lack of randomization allowed some other source of bias to influence the results. As the in-home measurements were largely consistent with the results of the laboratory tests, this possibility seems slight. Nonetheless, some uncertainty remains. In choosing to take regulatory action in the face of this uncertainty, CPSC implicitly made a policy determination that the potential risk to human health from continued use of UFFI insulation did not permit it to delay action until a large randomized study of UFFI homes could be completed. In vacating the UFFI ban, the court has substituted its own policy judgment for that of the agency. As a matter of administrative law, a court may reverse an agency's policy determination when that determination conflicts with the statutory mandate. It may also remand the issue to the agency for reconsideration if it finds procedural irregularity. It may not, however, merely replace the agency's policy with its own.

Does the Consumer Product Safety Act require the commission to conduct a controlled test from a randomly selected study population before imposing a product ban? Clearly the statute itself contains no explicit direction in this regard. Rather, both the statutory language and the legislative history indicate that considerable discretion is to be afforded the commission in its choice of study designs, so long as it bases its conclusions on generally reliable data.

Declaring that "it is not good science to rely on a single experiment," the court also found the commission's "exclusive reliance" on the CIIT rat bioassay in its projection of human cancer risk to be "unsupportable" (*14*). The extrapolation of animal data to predict human cancer risk is ultimately an issue of policy; "good science" is simply unable to provide a precise calculation of formaldehyde's carcinogenicity in humans. Consistent with the federal cancer policy set forth in the Regulatory Council statement, CPSC based its projections on a single, well-conducted animal bioassay. Although the court makes no mention of the Regulatory Council statement in its review of the commission's action, its rejection of that action is an implicit repudiation of carefully established federal administrative policy. All indications are that the court did not base this position on its reading of the commission's statutory mandate, but rather on its own understanding of scientific methodology. As such, the court has confused science with science policy, and has once again substituted its policy judgment for that of the agency.

In sum, though we must emphasize that we express no opinion as to the other aspects of the commission's decision, nor of the court's review thereof, we find the Fifth Circuit's analysis to be unpersuasive in its evaluation of CPSC's cancer risk assessment for formaldehyde.

Conclusion

Reasoned decision-making has evolved as a common standard for judicial review of agency action, and is a particularly appropriate criterion by which to evaluate the conduct of agencies responsible for protecting public health by regulating exposure to toxic substances. Although it was initially applied to decisions to take regulatory action, this standard has been increasingly applied to decisions not to act as well. This is a welcome development. In these antiregulatory times, decisions not to act are becoming more numerous, and adequate review is needed to ensure that the agencies adhere to their statutory mandates.

This review of the OSHA and EPA actions demonstrates the need to examine scientific determinations carefully, lest social policy decisions be hidden in alleged assessments of technical or scientific fact.

Finally, the formaldehyde case raises important questions about the proper status for an environmental agency. Of the three agencies examined here, only the one structured as a commission acted responsibly. Recent concern over the political manipulation of environmental agencies has prompted proposals to convert EPA into a "hybrid commission." Although structural changes can help insulate an agency from political influence, continued judicial and congressional scrutiny of Executive Branch agencies may—at least for the short term—provide the most practical check on agency impropriety. The courts and Congress thus must take a "hard look" to ensure that agencies exercise reasoned decision-making in their approach to toxic substance control.

References and Notes

1. Federal Panel on Formaldehyde, *Environ. Health Perspect.* 43, 139 (1982).
2. *Greater Boston Television Corp.* v. *Federal Trade Commission*, 444 Fed. Rep. 2nd ser. 841, 852 (D.C. Circuit Court, 1970), certiorari denied, 403 U.S. 923 (1971). See also: *Motor Vehicle Manufacturers Association* v. *State Farm Mutual Automobile Insurance Co.*, *U.S. Law Week* 51, 4953 and 4960 (1983), where the Supreme Court held that an agency must perform a "reasoned analysis."
3. *W.W.H.T., Inc.* v. *Federal Communications Commission*, 656 Fed. Rep. 2nd ser. 807 and 817 (D.C. Circuit Court, 1981).
4. 15 U.S. Code, §2603(f) (1976).
5. J. Todhunter himself has testified that when he arrived at EPA in July 1981 he was informed that the agency would take no regulatory action on formaldehyde.
6. N. A. Ashford, C. W. Ryan, C. C. Caldart, *Harv. Environ. Law Rev.* 7, 297 (1983).
7. ——, *ibid.*, pp. 329–333; U.S. Congress, Committee on Science and Technology, *Review of the Scientific Basis of the Environmental Protection Agency's Carcinogenic Risk Assessment of Formaldehyde* (98th Congress, 1st Session, 1983); F. Perera and C. Petito, *Science* 216, 1285 (1982).
8. 5 U.S. Code, appendix I (1976).
9. *United States Lines, Inc.* v. *Federal Maritime Commission*, 584 Fed. Rep. 2nd ser. 519 and 540, note 8 (D.C. Circuit Court, 1978).
10. *Securities and Exchange Commission* v. *Chenery Corp.*, 318 U.S. 80 and 94 (1943).
11. Regulatory Council, *Fed. Regist.* 44, 60,038 (1979).
12. "Review process for scientific, informational, and educational documents" (Order 2200, Environmental Protection Agency, Washington, D.C.), p. 3.
13. 28 U.S. Code, 1658(c) (1976).
14. *Dry Color Manufacturers Association, Inc.* v. *Department of Labor*, 486 Fed. Rep. 2nd ser. 98 and 104 (Third Circuit Court, 1973).
15. *Gulf South Insulation* v. *Consumer Product Safety Commission*, 701 Fed. Rep. 2nd ser. 1137 (Fifth Circuit Court, 1983).
16. All the primary source material referred to in this article was cited in full in our detailed treatment of this topic (6). For convenience, we included citations here only where we quoted directly from the source material or where we felt the citation to be particularly important.

ATTACHMENT D

Advisory Committees in OSHA and EPA: Their Use in Regulatory Decisionmaking

Nicholas A. Ashford

Federal agencies regulating the production and use of toxic substances increasingly have utilized citizen advisory committees to help shape the form of that regulation. Both the U.S. Occupational Safety and Health Administration (OSHA) and the U.S. Environmental Protection Agency (EPA) turn to such committees for recommendations on a variety of subjects, and the advisory committee has become an especially important source of federal policy on toxic substances. Recently, the discovery of a Reagan administration "hit list" naming many members of EPA's Science Advisory Board (SAB) whose views were no longer "acceptable" raised concern about questionable political manipulation of government advisory committees in general.[1] This article examines the creation and use of advisory committees in the regulation of toxic substances in manufacturing, and suggests mechanisms to insure and improve the effectiveness and public service functions of of these and similar committees.

History and General Functions of Advisory Committees[2]

An advisory committee is a group of citizens appointed to provide input to governmental decisionmaking on a particular subject or issue. Although the U.S. government made use of citizen advisory groups even in the 1700s, widespread use of advisory committees did not occur until this century. Beginning with the administration of Theodore Roosevelt, American presidents began to rely on citizen advisory committees to assist in the formulation and implementation of federal policy. More recently, an increase in the number of regulatory agencies has been accompanied by a concomitant rise in the number of advisory committees that provide input to those agencies, especially in environmental regulation.

Awareness of increased reliance on advisory committees has elicited a mixed response from the legislative and executive branches. Concerned that advisory committees can cross the line between advice and improper influence, the U.S. Congress passed in 1972 the Federal Advisory Committee Act (FACA).[3] Although FACA embraced the advisory committee as a "frequently . . . useful and beneficial means of furnishing expert advice, ideas, and diverse opinions to the Federal Government," Congress nonetheless declared that "the need for many existing advisory committees has not been reviewed," and concluded that the creation and operation of advisory committees should be more strictly controlled.[4] Accordingly, the Act requires that new advisory committees be kept to a "necessary" minimum; that advisory committees be terminated when they have served their purpose; that the establishment, operation, administration, and duration of advisory committees be subject to uniform procedures; and that relevant information regarding advisory committees be made available to the public.

In both the present and previous administrations, the executive branch has displayed an inconsistent

---

Nicholas A. Ashford is Associate Professor of Technology and Policy, and the Director, Center for Policy Alternatives, Massachusetts Institute of Technology, Cambridge, MA 02139. He is a former Chairman of the National Advisory Committee on Occupational Safety and Health and a former member of the Science Advisory Board of the Environmental Protection Agency.

© 1984 by the Massachusetts Institute of Technology and the President and Fellows of Harvard College. Published by John Wiley & Sons
Science, Technology, & Human Values, Volume 9, Issue 1, pp. 72–82 (Winter 1984) CCC 0162-2439/84/010072-11$04.00

attitude toward advisory committees. The Carter administration encouraged the increased use of panels or groups of experts to solve difficult regulatory questions, but it discouraged the creation of new advisory committees. Under the Heritage Foundation's blueprint for government reorganization in the Reagan administration, the existing advisory groups are seen as essential to the missions of the EPA, but OSHA committees are criticized. To the degree that an administration regards advisory committees as extensions of the agencies they serve, such love–hate relationships may be inevitable.

Throughout its history, the advisory committee has served two general functions. First, it has provided the federal government with a means of obtaining expert advice on a wide range of issues at relatively little cost.[5] This function has been of critical importance in the regulation of toxic substances. As the federal government has endeavored to protect the public health through the control of toxic substances, it has entered into an area of complex scientific, technical, and economic decisionmaking. Advisory committees provide the expertise that such decisions require.

By providing a means through which public opinion on a particular issue can be made known to responsible officials, advisory committees also have often served a "democratic" function. For many years, however, the advisory committees used for this purpose were drawn almost exclusively from the more privileged social and economic classes, and failed to provide an accurate portrayal of public opinion. Beginning with the administration of Lyndon Johnson, the agencies have broadened the base from which advisory committees are drawn, selecting women and more representatives of divergent social, economic, and ethnic backgrounds.

Toxic Substance Advisory Committees

In the area of toxic substance regulation, the "democratic" function of advisory committees is mandated by statutory directives that such committees be "balanced" among differing points of view. However, the particular kinds of tasks assigned to these committees also affect their nature and accomplishments. Toxic substance advisory committees may satisfy one or more of the following purposes: (1) to bring needed scientific or technological expertise to the agency's decisionmaking process; (2) to provide a mechanism for reaching a consensus on difficult-to-resolve scientific or technological issues; (3) to provide a mechanism for policy guidance when traditional factual resolution of scientific or technological issues is not possible, or (4) to provide a means of expanding the participation of interested or affected parties.

A committee of technical experts addressing the toxicity of carbon monoxide or alternative ventilation technologies, for example, might be constituted to meet the first purpose. Here, if there is little real disagreement on the relevant scientific or technical issues, the committee guides the agency to the latest and best information. When scientific or technical issues are difficult to resolve—for example, on the question of whether saccharin is a human carcinogen—the advisory committee can provide a forum for technical experts and attempt to achieve consensus on what is the "best" scientific judgment.

When the "factual" resolution of a scientific or technological issue is not possible in the traditional sense, the advisory committee provides a mechanism for policy guidance. This category encompasses many important issues in toxic substance regulation, such as the extrapolation of animal test data to humans; the interpolation of high-dose data to low-exposure conditions; the usefulness of short-term *in vitro* tests for assessing carcinogenicity; the reversibility of cell transformation induced by carcinogens; the distinction between benign and malignant tumors; and the prediction of technological innovation in response to regulation. Here, in the absence of satisfactory concrete scientific evidence, the final regulatory decision in each case must be based upon certain assumptions that concern science but are grounded in social policy determinations.[6] If no evidence exists to link a substance's carcinogenicity in animals to cancer in humans, then an advisory committee renders policy advice whenever it recommends permissible human exposure levels for that substance. Such a recommendation, although (presumably) guided by the animal data, rests ultimately on a balancing of social attitudes toward risk and utility, rather than on a mechanical evaluation of technical data.

Finally, in its most "democratic" sense, an advisory committee can facilitate the participation of interested parties in the regulatory decisionmaking process. This participation serves the political purpose of fair representation and could defuse subsequent adversary interactions. By raising the consciousness of technical experts to alternative views, the advisory committee system may also facilitate the entry of technical people into the regulatory agencies as permanent or "rotator" staff.

When scientific judgment is subject to prejudices and bias, or where difficult judgment calls vary widely and where divergent but not clearly incorrect points of view exist, the distinction so clearly shown in these functions—between fact-finding and fair process—begins to blur. As federal appellate courts have indicated in their review of OSHA cases, issues on the frontiers of scientific knowledge are not factual determinations in the usual sense; rather, they are decisions of social policy, and are legislative rather than judicial in character.[7] As advisory committees are deeply immersed in policy issues, the importance of composition that includes a variety of opposing viewpoints increases, lest committee policies serve only a narrow set of interests.

The Legal Framework for OSHA and EPA Advisory Committees

As noted above, the Federal Advisory Committee Act sets forth general guidelines and procedures applicable to all federal advisory committees. Not only does the Act require open meetings, detailed transcripts, a limited right of public participation, and the attendance of a federal government representative at advisory committee meetings, but Sections 5(b)(2) and 5(c) also state that committee membership should be "fairly balanced in terms of points of view represented and the functions to be performed." The recommendations of an advisory committee are, except where otherwise specifically authorized by statute, to be "advisory" only. More specific language dealing with toxic substances committees occurs in the Occupational Safety and Health Act (OSH Act) and in the Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDA).[8] In addition, EPA's Office of Toxic Substances has created an advisory committee. These advisory committees and subcommittees (see Table 1) fall into three general categories: *"permanent" advisory committees* created by statute to advise agencies on science, technology, or general policy issues; *"quasipermanent" committees*, usually created administratively, to advise agencies on science, technology, or general policy issues; and *"ad hoc" committees*, created either by statute or administratively, to advise agencies on a *specific* issue of science, technology, or policy.

Table 1. U.S. toxic substances advisory committees.[a]

	OSHA		EPA	
Permanent	NACOSH		SAB	
Quasipermanent				ATSAC
Ad hoc		Specific standards committees		
Policy-oriented	X	X		X
Science/technology		X	X	
Balanced	X	X		X
Expert only			X	

[a] Reprinted by permission of the publisher, from *Law and Science in Collaboration*, edited by J.D. Nyhart and Milton M. Carrow (Lexington, MA: Lexington Books, D.C. Heath and Company, Copyright 1983, D.C. Heath and Company).

Section 7(a) of the Occupational Safety and Health Act establishes a mandatory, permanent, "balanced" advisory committee known as the National Advisory Committee on Occupational Safety and Health (NACOSH) to advise the Secretary of Labor and the Secretary of Health and Human Services on general issues pertaining to the administration of the OSH Act. The committee's twelve members are drawn from management, labor, occupational safety and health professionals, and the public, and are selected "upon the basis of their experience and competence in the field of occupational safety and health." NACOSH is required to hold no fewer than two meetings during each calendar year.

In addition, the OSH Act makes provision for the creation of limited-lifetime, "balanced," *ad hoc* advisory committees to consider specific subjects related to the setting of occupational standards. The authority for such committees is found in Section 7(b) of the Act, which empowers, but does not require, the Secretary of Labor to appoint special advisory committees "to assist him in his standard-setting function under Section 6." Each of these committees is to have no more than fifteen members, and is to be balanced equally between "persons qualified by experience and affiliation to present the viewpoint of the employers involved" and "persons similarly qualified to present the viewpoint of the workers involved." In addition, an *ad hoc* committee must include at least one representative of a state health and safety agency, and may include other persons "who are qualified by knowledge and experience to make a useful contribution," as long as the number of such representatives does not exceed the number from federal or state agencies.

Although the Environmental Protection Agency established a Science Advisory Board (SAB) administratively in 1974, that Board was subsequently established by statute in the Environmental Research, Development, and Demonstration Authorization Act. The original Board consisted of five standing committees and an executive committee. Under the Reagan administration, however, the EPA reduced the number of standing committees to three. By statute, these committees are to meet periodically with the EPA Administrator "to provide advice . . . on the scientific and technical aspects of environmental problems and issues." Their membership is to be "a body of independent scientists and engineers of sufficient size and diversity to provide a range of expertise required to assess the scientific and technical aspects of environmental issues,"[9] and additional *ad hoc* committees may be drawn from the members.

EPA's regulation of toxic substances is also assisted by an administratively created advisory committee known as the Administrator's Toxic Substance Advisory Committee (ATSAC). This quasipermanent, "balanced" committee focuses primarily on issues of policy rather than issues of science. According to its charter, ATSAC is to advise the EPA "on policy, technical and procedural matters relating to the environmental, economic, and social aspects" of implementing the Toxic Substances Control Act (TSCA), and to "consider and comment on proposals for rules and regulations." However, the committee is directed to "generally defer" on scientific matters to the Science Advisory Board. The committee's sixteen members are to be drawn, "in appropriate balance," from three groups: (a) manufacturers, processors, and users of chemical substances; (b) environmental, health, and public interest organizations; and (c) other interested parties, "including, but not limited to, labor organizations, professional societies, and state and local interests." The committee is also authorized to form *ad hoc* subcommittees to deal with specific issues. ATSAC itself must hold from three to six meetings a year; the subcommittees are directed to meet "as needed."[10]

In addition to scientific and technical competence being represented in the committees themselves, both ATSAC and NACOSH typically request outside experts to address them on technical issues. Through these means, education of the committees is a continuing event. The SAB rarely operates in this manner.

Advisory Committee Performance

In general, advisory committees play a constructive role in developing regulatory policies for toxic substances. Members have usually been knowledgeable, and the deliberations valuable and instructive. All things considered, they have dealt well with the science and technology questions presented to them.

OSHA's twelve-member permanent committee, NACOSH, has been a major forum for discussing and clarifying controversial issues before unnecessary adversarial interactions occur. For example, NACOSH investigated the idea of adopting a generic cancer policy long before OSHA promulgated any formal rule. The committee served as an intellectual testing ground, and a review of its public transcripts reveals penetrating discussions of difficult questions on the science–law interface. Reproductive hazards were discussed with sophistication, and even internal "administrative" issues, such as research needs and opportunities and agency effectiveness, were addressed.

The *ad hoc* standard-setting committees have proved somewhat less integral to the OSHA process. An *ad hoc* committee is not always—in fact, usually is not—appointed as part of the standard-setting procedure. When a committee has been appointed, OSHA's response to committee recommendations has been mixed. On some occasions (for example, the coke oven emissions standards), OSHA has taken the committee's advice and based a standard on the recommendations. On other occasions, such as the early experiences with pesticide exposures, the agency has departed widely, and vigorously, from committee recommendations.

OSHA's reticence in utilizing standard-setting committees may stem, in part, from their transitory nature. Although the ability to appoint separate committees for different standards provides desirable flexibility on scientific and technical issues, it may be less than desirable for developing uniform policy and may lead to an uneven approach to standard-setting. A solution might lie with the appointment of a core of "standing" members who would serve on all *ad hoc* committees.

Unlike OSHA, EPA does not receive general policy advice on toxic substances from a broadly focused permanent committee. Its main advisory body, the Science Advisory Board, is concerned primarily with issues of science and technology rather than issues of policy. On issues related specifically to the implementation of the Toxic Substances Control Act, however, EPA regularly receives advisory committee recommendations on toxic substance policy from the Administrator's Toxic Substance Advisory Committee (ATSAC).[11] ATSAC has monitored the ongoing implementation of TSCA, and has addressed, among other issues, regulatory strategies for new and existing chemicals, testing rules, and the relationship between regulation and innovation in the chemical industry. Because EPA has taken no significant regulatory action (other than on PCBs) under TSCA, ATSAC's effectiveness is yet to be tested. Analysis of its transcripts, however, reveals intelligent, probing discussions that closely parallel those held by NACOSH. One striking feature of ATSAC is the presence on the committee of both environmental lawyers and scientists.

Because ATSAC must defer to the Science Advisory Board on technical issues, EPA's science advice in the area of toxic substances comes from the SAB. Here, in contrast to OSHA's standard-setting committees, *ad hoc* committees are drawn from the larger SAB membership, thus providing both flexibility and continuity. Although the board is charged with the responsibility for technical issues, it often deals with issues which touch on policy as well. In a broad sense, its activities are to include the review of EPA programs and strategies, the review of the scientific basis of proposed criteria documents, standards, limitations, and regulation, and the recommendation of new standards and programs. EPA records indicate that SAB activities in 1979 focused mainly on analyses of the scientific bases of proposed standards, on evaluations of the health effects of particular toxins, and on general issues of evaluation methodology and environmental modeling. EPA described the activities relevant to TSCA as follows:

> Analysis of the scientific data bases now in existence and new ones required for implementation of the Toxic Substances Control Act (TSCA) is the continuing activity of a permanent subcommittee. The subcommittee also is analyzing the potential of current and planned EPA research to provide necessary support for TSCA.[12]

Based on their performance to date, advisory committees appear to have the potential to make significant contributions to decisions on toxic substance regulation. Their chief contribution may lie in their facility to integrate and distinguish questions of science and questions of policy because transcripts of the NACOSH and ATSAC meetings reveal a growing conviction that uncertainty in science or technology does not preclude effective regulatory response to a problem. Naturally enough, however, committee members disagree about the type of response. Accordingly, the most heated committee discussions have centered on issues of policy, not science, even where the science has been uncertain.

The Fair Balance Issue[13]

Analysis of the legislative and administrative history of the adoption of the statutory requirement for fair balance suggests that it was intended to achieve the following objectives: (1) to increase the numbers of "individuals affected by agency action" as participants on advisory committees; (2) to avoid overrepresentation of a particular geographic region, university, industry, company, or discipline on any advisory committee; (3) to include more consumers and representatives of public interest groups as members, in an effort to balance industry representation; (4) to include more "nonexperts" (i.e., lay people) as members, but to ensure that they are interested and knowledgeable; and (5) to preclude a domination of the committee by any one viewpoint or interest that might give some private concerns special access to public policymakers.[14]

If there is a great potential for improving the regulatory process through the use of advisory committees, a similar opportunity exists for subverting that process through their misuse. Governments have sometimes used advisory committees for little more than implementing a decision made before the committee was established, either by appointing members who will merely "rubber stamp" government decisions, or by appointing influential community leaders whose support is needed for implementation of a government decision.[15] Until recently, OSHA and EPA appear to have avoided such blatant manipulation. OSHA has now replaced eleven of the twelve members on NACOSH, however, and EPA has retired practically all of its sixty SAB members, many who were on the previously mentioned "hit list."[16] Thus, even though the scientific experts may, as individuals, be protective of their professional standing, manipulation of advisory committees is possible by appointment of only "acceptable" members.

The key to such misuse is an agency's circumvention of the requirement of Section 5 of FACA that advisory committee membership be "fairly balanced in terms of the points of view represented." Although some observers have expressed doubt over the meaning of this provision,[17] the statute's plain language and the relevant legislative history give fairly clear signals of its intentions.[18] Fairness demands more than a token representation of an opposing viewpoint. The statute clearly anticipates a good faith effort at parity.[19] The Second Circuit Court of Appeals, echoing language found in the House of Representatives Committee Report explaining Section 5, has indicated that the provision's underlying purpose is to prevent any one point of view from "dominating" the consideration of an issue.[20] It should be realized that, of course, in advisory committee deliberations, consensus-building for policy recommendations generally avoids domination by a bare majority. To be effective, heavy consensus is required, and thus, unless the committee is heavily stacked, some imbalance is tolerable.[21]

In formulating an operational definition of "balance" to meet the FACA requirements, three criteria are suggested: competence, discipline, and bias/allegiance.[22] Balance in the effectiveness of technical argument surely requires equivalent *competence* or expertise among antagonists, yet experts as a group may need to be tempered by the participation of nonexpert members. Each *discipline* carries its own paradigmatic bias, and both nonexperts and several disciplines should be represented, the mixture depending on the committee's agenda or purpose. Finally, political, institutional, ethnic or sexual *bias or allegiance* should be adequately "balanced." Most of the attention in addressing the fair balance requirement seems to have been focused on this last criterion.

"Competence" Balance

Balance in the effectiveness of technical argument requires equivalent technical *competence* among those members who differ with regard to political or policy matters, and this, in turn, presupposes equivalent commitment to utilize that competence in fulfilling committee responsibilities. One of the easiest ways for an agency to secure a committee's adoption of a particular position is to appoint less-than-competent or uncommitted members to represent opposing positions. In addition, as one commentator has noted, committees may be stacked with "distinguished" members rather than those whose competencies relate to the agenda.[23]

Disciplinary Balance

A committee composed entirely of scientists is clearly not balanced between experts and nonexperts, but it also may not be balanced among technical *disciplines*, thereby masking a source of consistent bias. Asked by an agency, for example, to develop exposure standards for a chemical on which the evidence of human carcinogenicity is conflicting, scientists will tend to take a "conservative" posture. Inclined by both training and experience to adopt a "wait and see" attitude or to call for further study, these members might decline to express a position on carcinogenicity until more conclusive evidence is available. An agency that desires a conservative position on a question of toxic substance *policy* therefore stands a better chance of securing that position by submitting the issue to a purely *scientific* committee.

As a general rule, the more the issues facing an advisory committee are policy-related, the more its objectivity in considering those issues will depend on the degree to which committee membership is balanced on all relevant factors. Lack of balance among scientific subspecialties, however, can also affect the consideration of largely *scientific* issues. Suppose that an advisory committee is asked to evaluate the carcinogenic risk posed by exposure to vinyl bromide. Those scientists whose general research involves animal studies of carcinogenicity may view the risk differently than epidemiologists who study patterns of disease among humans or those scientists who develop short-term tests for mutagenicity for predicting carcinogenicity. Disciplinary bias can greatly affect the "scientific" determination of carcinogenicity because one kind of evidence may carry more weight than another.

Among toxic substance advisory committees, the EPA's Science Advisory Board is conspicuous for its lack of disciplinary balance. To the extent that the SAB delves into policy matters—such as recommending standards or assessing risk–benefit methodologies—this imbalance may pose a potentially serious problem. In part, the imbalance is the result of SAB's Congressional mandate. The enabling statute, ERDDA, specifies that SAB membership be drawn from persons "qualified by education, training, and experience to evaluate scientific and technical information on matters referred to the Board,"[24] a mandate that would appear to exclude nonscientists. The language does not, however, obviate the other balancing requirements of FACA. Rather than continuing to restrict membership to "scientists and engineers," EPA should properly seek a membership that represents a fair balance of other disciplines meeting the statutory criteria of technical competence. In addition, the SAB must be balanced on all relevant factors of bias or allegiance and competence.

Congress recently had the occasion to reaffirm its intention that FACA be applied to the SAB. An EPA appropriations bill, repeating the language of FACA, specifically required SAB membership to be "fairly balanced in terms of points of view represented" and required that such balance be achieved through the inclusion of members representing "the states, industry, labor, academia, consumers, and the general public."[25] On 22 October 1982, Ronald Reagan vetoed the bill and gave his objections to these requirements as the major reason.[26] In his veto message he stated:

> . . . This requirement runs counter to the basic premise of modern scientific thought as an objective undertaking in which the views of special interests have no role. The purpose of the Science Advisory Board is to apply the universally accepted principles of scientific peer review to the research conclusions that will form the basis for EPA regulations, a function that must remain above interest group politics.
>
> In addition, under the statutes governing actual promulgation of EPA rules, the Administrator is obligated to seek public comment from any and all interested parties and to weigh such comment in shaping final rules. That is the stage of the rulemaking process at which involvement of special interest viewpoints is appropriate, not the earlier stage of developing a sound scientific understanding of the research findings that may be relevant to a particular rulemaking or class of rules.[27]

Such a viewpoint assumes that only "neutral" scientists are appropriate, and further assumes that such persons exist.[28]

Despite the Presidential veto, Congressional efforts to achieve a fair balance on the SAB continue. Reportedly, the issue will be the subject of public hearings during the Fall 1983 session of Congress.[29]

"Bias/Allegiance" Balance

Balancing must also be achieved in the bias and allegiance of committee members. Although, broadly speaking, we are all affected by toxic substances regulation, some persons are more directly affected than others. Accordingly, FACA's legislative history indicates that the Act requires that industry representatives on a committee be balanced by representatives of the environmental movement.[30] Indeed, FACA's Section 5(b)(3) requires that "appropriate provisions" be taken to

> ensure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment.

FACA also acknowledges several general "bias" criteria, such as political orientation, institutional affiliation, race, sex, and geography. This aspect of the balancing requirement would appear to insulate advisory committee members from "political" removal, and might require a degree of membership continuity from administration to administration.

Perhaps because of Section 5(b)(3), bias and allegiance have received the greatest attention in agency efforts to balance committee membership. But such balancing may have been perfunctory. For example, one commentator reports that evaluations of prospective committee member's potential allegiances have usually not considered sources of employment, grants, and contracts.[31]

Given the potentially large number of relevant factors on which balance must be achieved, compliance with the fair balance requirement will sometimes be difficult. For scientific and technical advisory committees, the requirement of technical competence also narrows the pool of candidates from which the other relevant criteria must be satisfied. Mere difficulty, however, does not excuse noncompliance. If toxic substance advisory committees are truly to exercise the "independent judgment" that FACA requires, OSHA and EPA must be forthright and diligent in their efforts to achieve proper committee balance.

Fair balance alone will not insulate advisory committees from misuse. An agency may avoid *ad hoc* committees, for example, by merely failing to establish them. An agency may reduce the size of advisory committees, reduce their funding, or hold meetings only infrequently. It may refuse to cooperate with the committees by denying them timely access to agency records or personnel. And, of course, it may always simply ignore advisory committee recommendations. In each of these cases, however, the agency's antagonism toward the advisory committee will be more or less obvious. Only the lack of fair balance will enable an agency to subvert the advisory committee process while still *appearing* to be using it properly. It is this criteria, then, that merits special attention both by the public and by policy analysts.

Recommendations for Improving the Effectiveness of Toxic Substance Advisory Committees

To be effective, an advisory committee must not only provide objective, intelligent, and thoughtful advice to the agency, but the agency must also give due consideration to that advice, and to the advisory committee process, in the formulation of its regulatory policies. To achieve that effectiveness, advisory committees must satisfy several criteria. First, of course, they must have a balanced and committed membership. The committee must be provided the necessary independence within which to pursue its work, must be given adequate financial support, and must receive the full support and cooperation of its parent agency. And there must be a strong and independent chairperson to shepherd the advisory committee through its sensitive work. The absence of any one of these factors can render an advisory committee little more than an empty bureaucratic exercise.

The OSHA and EPA advisory committees discussed here would benefit from attention to each of these items. Aside from the fair balance issues, frequency of committee meetings, cooperation in agenda-setting, and continuity and longevity of committee membership should be considered. Ongoing advisory committees need to meet, on the average, every six weeks to two months if they are to consider the issues adequately. Currently, most toxic substance committees meet less frequently. NACOSH, for example, has met only twice in the twelve months preceding completion of this study.

Committee agendas are a critical factor, as well. If advisory committees have insufficient autonomy to determine the issues they will consider, important issues may be overlooked, and the advisory committee may cease to function as an independent body. Furthermore, interested, activist members may leave the committee in frustration. This is not to say that agenda-setting should be left solely to the committee. Rather, good faith cooperation between the agency and the committee will be the key to identifying those issues that should appear on the agenda.

Continuity is also an important factor. As members serve together on a committee, they build a personal relationship that can transcend individual political and disciplinary biases and help them to work more objectively and effectively toward the public interest. Thus, while the establishment of an "old boy" (or "old girl") network should be avoided, both OSHA and EPA should be more judicious in their replacement of advisory committee members. In addition to conflicting with the fair balance requirement, wholesale "political" replacements will serve only to lessen advisory committee effectiveness.

President Reagan's veto of a specific balancing requirement for the SAB was supported by both the National Academy of Sciences and the American Association for the Advancement of Science.[32] This support, in light of the history of the EPA "hit list," suggests that, driven by the desire to maintain the *illusion* of neutrality of science and scientists, the scientific community may, as a practical matter, prefer covert stacking to overt balancing. How, then, can such stacking and imbalance be avoided? If overt balancing cannot be maintained, an alternate course may be to require all advisory committee members to disclose not only their current professional affiliation but also their present and past consulting arrangements and other activities.[33] Full disclosure, at least, will let the public know more about the composition of a particular committee.

In the final analysis, the effectiveness of advisory committees may well depend on the degree to which their use is subjected to public scrutiny. The Federal Advisory Committee Act, the Federal Open Meetings Act, and the Freedom of Information Act all provide mechanisms through which citizens can monitor advisory committee proceedings. And legal channels are available to check agency abuse of the advisory committee process. Use of these channels, however, demands close attention to the details of administrative law. Legal challenges to arguably "unbalanced" advisory committee memberships have failed, for example, because the party mounting the challenge did not object to the unbalanced nature of the committee when it was originally constituted.[34] Continued and spirited citizen monitoring of advisory committees may therefore be a necessary predicate to legal action. Only with the help of a watchful citizenry and a concerned Congress can advisory committees fulfill their potential to serve the public interest.

Notes

1. See, for example, Howard Kurtz, "EPA Removed More than 50 Scientists on Conservative 'Hit List,'" *The Washington Post* (2 March 1983): A2; Eliot Marshall, "Hit List at EPA?" *Science*, Volume 219, Number 4590 (18 March 1983): 1303; "EPA 'Hit List' Fuels Agency Controversy," *Chemical and Engineering News*, Volume 61, Number 10 (7 March 1983): 5.
2. Detailed discussions of advisory committee history can be found in Clementine L. Kaufman, "A Sociohistorical View of Advisory Committees," unpublished, prepared for Charles F. Kettering Foundation Conference on Federal Advisory Committees (June 26, 27, 1981); Michael H. Cardozo, "The Federal Advisory Committee Act in Operation," *Administrative Law Review*, Volume 33, Number 1 (1981); and Richard A. Wegman, "The Utilization and Management of Federal Advisory Committees" (Charles F. Kettering Foundation, 1983).
3. 5 U.S.C. App. I.
4. 5 U.S.C. App. I, Section 2.
5. See Cardozo, *op. cit.*, p. 51: "[The alternative cost of outside consultants] would far exceed the current expenditures for travel and per diem of all the members of advisory committees."
6. For a discussion of the distinction between science and science policy determinations in the evaluation of formaldehyde's carcinogenicity, see Nicholas A. Ashford, C. William Ryan, and Charles C. Caldart, "A Hard Look at Federal Regulation of Formaldehyde: A Departure from Reasoned Decisionmaking," *Harvard Environmental Law Review*, Volume 7, Number 2 (1983): 297.
7. See *Industrial Union Department, AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1964):*

   > *. . . some of the questions involved . . . are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination. Decision making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual analysis.*

   See also *Society of the Plastics Industry, Inc. v. OSHA*, 509 F.2d 1301, 1308 (2nd Cir. 1975).
8. OSH Act: 28 U.S.C., Sec. 651, *et. seq.*; ERDDA: 42 U.S.C., Sec. 4351a, *et. seq.* The SAB was created by Sec. 4365.
9. United States Environmental Protection Agency, Advisory Committee Charter, Science Advisory Board (19 October 1979), as found in EPA, "U.S. Environmental Protection Agency Advisory Committees: Charters, Rosters, and Accomplishments" (January 1980): 30–32; quotations are from paragraphs 3 and 4.
10. United States Environmental Protection Agency (EPA), Advisory Committee Charter, Administrator's Toxic Substances Advisory Committee (22 November 1979), as found in EPA, "U.S. Environmental Protection Agency Advisory Committees: Charters, Rosters, and Accomplishments" (January 1980): 1–2; quotations are from paragraphs 2, 3, and 4.
11. EPA may also receive regular policy advice from advisory committees created to assist its implementation of the Clean Air Act and the Federal Insecticide, Fungicide, and Rodenticide Act. The activities of these committees are beyond the scope of this article.
12. EPA, "U.S. Environmental Protection Agency Advisory Committees: Charters, Rosters, and Accomplishments" (January 1980): 39–40.
13. For a legal history of the fair balance requirement, see Wegman, *op. cit.*, pp. 180–191, and Cardozo, *op. cit.*, p. 15.
14. See Wegman, *op. cit.*, p. 185.
15. See, e.g., Kaufman, *op. cit.*, pp. 6–7.
16. See note 1 above. At the hearings of the House Committee on Science and Technology, Subcommittee on Natural Resources, Agricultural Research and Environment, on 19 March 1982, EPA Ad-

ministrator Anne Gorsuch was asked by Congressman James H. Scheuer why she had replaced most of the SAB members. She referred the question to Deputy Administrator John Hernandez who replied, "our plans are not to appoint them because we believe there are a lot of people with equal abilities in the field." [Fiscal Years 1983 and 1984 Environmental Protection Agency Research and Development Authorization, 97th Congress, 2nd Session 124 (1982): 220–221.]

17. See Cardozo, *op. cit.*, p. 55: "Doubt has existed . . . whether this means that various political, ethnic, geographic, educational, and societal points of view are to be represented, or that the members should have a balance of relevant training, experience and professional competence." For a similar viewpoint, see Kit Gage and Samuel S. Epstein, "The Federal Advisory Committee System: An Assessment," *Environmental Law Report*, Volume 7 (1977): 5001 and 5004: "Must a committee be divided evenly by interest sectors or is one member, with a viewpoint different from the majority, sufficient to balance a committee?"
18. See the text accompanying note 14 above.
19. Responsibility for advisory committees now rests with the General Services Administration (GSA). An interim rule issued by GSA requires that the agency consider for membership: "a cross section of interested persons and groups with demonstrated professional or personal qualifications or experience to contribute to the functions and tasks to be performed."

    The rule also provides that other persons may be considered for membership, "where such participation is necessary to obtain divergent points of view that are relevant to the business of the advisory committee." 48 *Federal Register* 19328 (23 April 1983), §101-6.1007(a)(2)(iii).
20. In *National Nutritional Foods Association v. Califano*, 603 F.2d 327 (2nd Cir., 1979), an industry group challenged the composition of an advisory committee convened to provide recommendations on the question of whether consumer warnings should be placed on packaged dietary supplements. The plaintiff argued that the committee, which was comprised solely of physicians, was in violation of the fair balance requirement. Although the Second Circuit upheld a federal district court's dismissal of the suit on procedural grounds, it was nonetheless sympathetic to the fair balance issue. Noting that physicians were "understandably leaning in favor of medical supervision of the use of protein supplements to conquer obesity" (603 F.2d at 334), the court declared that the committee's unbalanced nature "directly implicates the concern Congress addressed in Sec. 5(b)(2) and (3) of the Act, that agency action might be dominated by one particular viewpoint" (603 F.2d at 336). This language is similar to that found in the committee report explaining the House version of the bill, from which Section 5 was drawn. That report points to "the danger of allowing special interest groups to exercise undue influence upon the Government through the dominance of advisory committees," and indicates that Section 5 was intended to prohibit both a "lack of balanced representation of different points of view" and a "heavy representation of parties whose private interests could influence their recommendations" [HR 92-1017, 92nd Congress, 2nd Session, 1972, as found in *U.S. Code Congressional & Administrative News*, 92nd Congress, 2nd Session, 3491, 3496 (1972)]. Discussions of the relevant legislative history can be found in Cardozo, *op. cit.*, p. 15; Wegman, *op. cit.*, pp. 180–185; and Richard A. Wegman and David P. Lambert, "Report on Federal Advisory Committees: Background and Summary of Significant Findings and Recommendations," unpublished (15 March 1982), p. 25. A recent decision of the United States District Court for the District of Columbia, *National Anti-Hunger Coalition v. Executive Committee of the President's Private Sector Survey on Cost Control*, 557 F.Supp. 529 (D.D.C. 1983), suggests that an agency may be able to narrow the applicability of the fair balance requirement by narrowing the *issue* to be considered by the advisory committee. The court appears to have held that if the issue is narrow and "technical" enough to permit proper resolution without resort to the fair balance requirement, that requirement becomes meaningless. This rationale appears inconsistent with the language and history of FACA, and the case is presently on appeal to the United States Court of Appeals for the District of Columbia (Docket Number 83-1248). The ultimate impact of the district court opinion is thus not yet known. Nonetheless, as the subsequent discussion in this article indicates, the issues before toxic substances advisory committees will rarely, if ever, be so narrow and technical as to warrant a suspension of fair balance.
21. The *wholesale replacement* of advisory committee members on the SAB suggests that the replacement may have resulted in stacking.
22. These three "balance" criteria suggested by the author are also discussed in an unpublished report on advisory committees prepared by a team of consultants to the Charles F. Kettering Foundation. See *Criteria for the Selection of Advisory Committee Members*, C.F. Kettering Foundation, 20 August 1981.
23. Kaufman, *op. cit.*, p. 17.
24. 42 U.S.C., Sec. 4365.
25. H.R. 6323, Sec. 6(b)(2), 97th Congress, 2nd Session (18 May 1982).

26. R. Jeffrey Smith in *Science*, Volume 218, Number 4573 (12 November 1982): 663.
27. Ronald Reagan, Veto Message of S.2577, 22 October 1982.
28. Interestingly, the Reagan veto was urged both by Frank Press, President of the National Academy of Sciences (letter from Frank Press to George A. Keyworth, Science Advisor to the President, 25 October 1982), and William D. Carey, Executive Officer, American Association for the Advancement of Science (letter from William D. Carey to George A. Keyworth, 22 October 1982).
29. Personal communication with the Legislative Staff of the U.S. House of Representatives, Subcommittee on Natural Resources.
30. The House committee report on FACA, cited above in note 20, makes specific mention of the activities of the Advisory Committee on Federal Reports, which had met with government officials to discuss a "national industrial wastes inventory questionnaire." As noted in the committee report, "only representatives of industry were present" at the meeting. The report decries the lack of "representatives of conservation, environment, clean water, consumer, or other public interest groups" at the meeting, and indicates that such an imbalance would be prohibited by FACA.
31. Gage and Epstein, *op. cit.*, p. 5004.
32. See note 28 above.
33. This compromise was discussed at a recent roundtable discussion of EPA regulatory policy; see "Examining the Role of Science in the Regulatory Process," *Environment*, Volume 25, Number 5 (1983): 6.
34. The need for diligence in seeking to enforce FACA is illustrated by the plight of the plaintiff in *Physicians' Education Network, Inc., v. The Department of Health, Education and Welfare*, 653 F.2d 621 (D.C. Cir., 1981). The Physicians' Network, representing a group of ophthalmologists, challenged the composition and activities of an advisory committee that had recommended an extension of Medicare reimbursement to eye care performed by optometrists. Without reaching the question of whether the allegations were sufficient to raise an issue under FACA, the court held that the Physicians' Network lacked the requisite "standing" to maintain the lawsuit because it had failed to object to the alleged FACA violations before the issuance of the report:

> Physicians' does not allege that it sought and was denied participation in the panel's meetings, or that it sought and was denied representation on the panel itself. Allegations of this kind have been found sufficient in other cases to support standing to invoke the provisions of the Federal Advisory Committee Act against an agency. Far from acting promptly, Physicians' did not sue until October 1979, more than three years after the report was delivered to Congress in July 1976. (653 F.2d at 623)

See also *National Nutritional Foods Association v. Califano, supra* at note 20; *Metcalf v. National Petroleum Council*, 553 F.2d 176 (D.C. Cir. 1977); *Center for Auto Safety v. Tiemann*, 414 F. Supp. 215, 220 (D.D.C., 1976); remanded on other grounds, 580 F.2d 689 (D.C. Cir. 1978); *Nader v. Baroody*, 396 F. Supp. 1231–1232 (D.D.C., 1975).

Mr. SCHEUER. Thank you very much.

Dr. Rodricks, if you would take 7 or 8 minutes and sum up your testimony, we will go to Dr. Huber. Then we will have some questions for all of you.

Dr. RODRICKS. Mr. Chairman and members of the subcommittee, I highly appreciate the opportunity to offer some comments on H.R. 4192 and the scientific and policy context in which it appears. My name is Joseph Rodricks. I am a principal of Environ Corp. here in Washington. I came to consulting and risk assessment after 15 years with the Food and Drug Administration. I should also mention that I served on the Committee for the Institutional Means for the Assessment of Risk to the Public Health of the National Research Council. Although I do not speak here for the NRC, my remarks are heavily influenced by the recommendations contained in the committee's 1983 report, "Risk Assessment in the Federal Government."

As noted in the introduction to the proposed bill, predictive-risk assessment now plays a central role in regulatory decisionmaking, and I believe its uses will surely increase. Although it is a highly uncertain scientific enterprise, and I agree with Dr. Ashford that it certainly includes a number of value judgments, there appear to me to be no better or more systematic means available to organize and report scientific information on environmental hazards to allow identification of those hazards that need to be controlled and the extent of the control necessary to protect human life and the environment.

The bill's principal objective, improving the conduct and use of risk assessment in the regulatory process, I think is both timely and commendable, and most of the activities called for in the bill should assist achieving this objective. There are, however, several aspects of the proposed bill that I suggest might be reconsidered.

First, I address what might appear to be a relatively minor matter, that of definitions. Because risk assessment is still a relatively immature subject, a consensus does not appear to have emerged regarding its boundaries and its relationship to other risk related activities. The NRC has defined risk assessment as "the characterization of the potential public health consequences of exposure to a particular substance. This characterization may include where possible quantification of the probability of adverse condequences."

This definition of risk assessment, which is essentially identical to the definition of risk analysis set forth in the bill, has been adopted by several regulatory agencies and is becoming increasingly accepted in the scientific community. The NRC Committee also distinguishes risk assessment from risk management; the latter activity includes evaluation of the public health significance of an assessed risk, which may include comparative risk evaluation, and the options for control of risks judged to be significant. The NRC Committee concluded that maintenance of a clear distinction between assessment and management is critical to sound decisionmaking. As defined in the bill, risk evaluation would appear to be a major component of the risk management process in that it involves attempts to establish the so-called acceptability of a given level of risk. The bill, of course, defines risk assessment to include both analysis and evaluation.

Although these matters of definition may seem relatively trivial, I suggest that adoption of the definitions of risk assessment and risk management recommended by the NRC would contribute substantially to improving understanding of these subjects within the concerned scientific and regulatory communities and also by the general public. Moreover, it appears that further work on definitions may be need to clarify the specific requirements of title I of the bill.

Thus, although the drafters of the bill clearly intend that the proposed demonstration projects deal with risk assessment, which by their definitions includes both analysis and evaluation, it is not clear to me that the very important distinction between assessment of risks, as defined by NRC, and the types of policy analysis needed to support a risk management decision is adequately maintained.

For example, some of the requirements of the demonstration project seem directed at risk assessment, while others seem concerned with the management process. I do not find the language clear on this distinction. Unless that distinction is maintained, I suggest the value of the demonstration projects will be greatly diminished. I should add that I support the specific objectives of the demonstration projects, and only call for clarification of the content of their various components.

I also note that several aspects of the proposed project have already been studied and reported upon by the NRC Committee. These include means for making the risk assessment activities of the Federal agencies more consistent, more understandable to the public, and for maintaining the distinction between management and assessment. I urge that the demonstration projects include a requirement that the agencies consider the recommendations of the NRC Committee on these several issues and to take them into account when undertaking their own studies.

I also note that although title II now appears to have been stricken from the bill, the desirability of a central risk-assessment board was studied by our committee at the NRC. We concluded that such a board should be created, but that its activities should not include review of agency risk assessments on specific substances. It should devote its activity to the development of uniform Government-wide guidelines for risk assessment. If that matter comes up again, I hope the recommendations of the NRC Committee be considered there.

Finally, I should like to make some remarks about what I see as potentially the most important requirement of this bill. Risk assessors are being asked to predict risks based on limited information and inadequate fundamental knowledge. Although risk assessors can certainly do much to improve the quality of their risk predictions, they cannot possibly make them more accurate without a great deal more knowledge than we now have.

There is only one remedy for this state of affairs, and that is the development of programs of scientific research designed to investigate the major areas of uncertainty in risk assessment. I am not referring here simply to more data collection, but to the development of new research methods that can be used to collect the specific types of data needed to fill major gaps in fundamental knowledge.

This bill provides, at least to my knowledge, the first opportunity to link in a systematic manner the needs of the risk assessor to the capabilities of the laboratory, and I think this is a highly laudable goal. I also note that the bill calls for a research agenda for risk assessment, as this term is currently defined in the bill. This suggests that the agencies also investigate the types of social or policy research needed to make better risk management decisions, if I interpret the bill correctly. If this is so, I suggest more explicit recognition of this point in the language of the bill.

Although I have made certain suggestions that some aspects of the bill's requirements need to be more carefully defined, I should reemphasize that I believe its fundamental objectives and approach are valuable additions to the continuing effort to improve both the scientific and policy aspects of regulatory decisionmaking.

Thank you.

[The prepared statement of Dr. Rodricks follows:]

TESTIMONY OF JOSEPH V. RODRICKS, PH.D.

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMITTEE, I HIGHLY APPRECIATE THE OPPORTUNITY TO OFFER SOME COMMENTS ON H.R. 4192, AND THE SCIENTIFIC AND POLICY CONTEXT IN WHICH IT APPEARS. MY NAME IS JOSEPH RODRICKS, AND I AM A PRINCIPAL OF ENVIRON CORPORATION, A WASHINGTON CONSULTING FIRM SPECIALIZING IN RISK ASSESSMENT. I CAME TO CONSULTING AFTER 15 YEARS WITH THE FOOD AND DRUG ADMINISTRATION, IN WHICH I HELD A NUMBER OF POSITIONS IN WHICH I WAS RESPONSIBLE FOR THE CONDUCT OF RISK ASSESSMENT AND ITS USE IN REGULATORY DECISION-MAKING. I SHOULD ALSO MENTION THAT I SERVED ON THE COMMITTEE ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO THE PUBLIC HEALTH OF THE NATIONAL RESEARCH COUNCIL. ALTHOUGH I DO NOT SPEAK FOR THE NATIONAL RESEARCH COUNCIL, MY REMARKS ARE HEAVILY INFLUENCED BY THE RECOMMENDATIONS CONTAINED IN THE COMMITTEE'S 1983 REPORT "RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS."

AS NOTED IN THE INTRODUCTION TO THE PROPOSED BILL, PREDICTIVE RISK ASSESSMENT NOW PLAYS A CENTRAL ROLE IN REGULATORY DECISION-MAKING, AND ITS USES WILL SURELY INCREASE. ALTHOUGH RISK ASSESSMENT IS A HIGHLY UNCERTAIN SCIENTIFIC ENTERPRISE, THERE APPEAR TO BE NO BETTER OR MORE SYSTEMATIC MEANS AVAILABLE TO ORGANIZE AND REPORT SCIENTIFIC INFORMATION ON ENVIRONMENTAL HAZARDS TO ALLOW IDENTIFICATION OF THOSE HAZARDS THAT NEED TO BE CONTROLLED AND THE EXTENT OF CONTROL NECESSARY TO PROTECT HUMAN LIFE AND THE ENVIRONMENT. THE BILL'S PRINCIPAL

OBJECTIVE -- IMPROVING THE CONDUCT AND USE OF RISK ASSESSMENT IN THE REGULATORY PROCESS -- IS BOTH TIMELY AND COMMENDABLE, AND MOST OF THE ACTIVITIES CALLED FOR IN THE BILL SHOULD ASSIST ACHIEVING THIS OBJECTIVE. THERE ARE, HOWEVER, SEVERAL ASPECTS OF THE PROPOSED BILL THAT I SUGGEST SHOULD BE RECONSIDERED.

FIRST, I ADDRESS WHAT MIGHT APPEAR TO BE A RELATIVELY MINOR MATTER -- THAT OF DEFINITIONS. BECAUSE RISK ASSESSMENT IS STILL A RELATIVELY IMMATURE SUBJECT, A CONSENSUS DOES NOT APPEAR TO HAVE EMERGED REGARDING ITS BOUNDARIES AND ITS RELATIONSHIP TO OTHER RISK-RELATED ACTIVITIES. THE NATIONAL RESEARCH COUNCIL (NRC) HAS DEFINED RISK ASSESSMENT AS THE "CHARACTERIZATION OF THE POTENTIAL PUBLIC HEALTH CONSEQUENCES OF EXPOSURE TO A PARTICULAR SUBSTNCE." THIS CHARACTERIZATION MAY INCLUDE, WHERE POSSIBLE, QUANTIFICATION OF THE PROBABILITY THAT ADVERSE CONSEQUENCES WILL OCCUR. THIS DEFINITION OF RISK ASSESSMENT, WHICH IS ESSENTIALLY IDENTICAL TO THE DEFINITION OF "RISK ANALYSIS" SET FORTH IN THE BILL, HAS BEEN ADOPTED BY SEVERAL REGULATORY AGENCIES AND IS BECOMING INCREASINGLY ACCEPTED IN THE SCIENTIFIC COMMUNITY. THE NRC COMMITTEE ALSO DISTINGUISHES RISK ASSESSMENT FROM RISK MANAGEMENT; THE LATTER ACTIVITY INCLUDES EVALUATION OF THE PUBLIC HEALTH SIGNIFICANCE OF AN ASSESSED RISK (WHICH MAY INCLUDE COMPARATIVE RISK EVALUATIONS), AND THE OPTIONS FOR CONTROL OF RISKS JUDGED TO BE SIGNIFICANT. THE NRC COMMITTEE CONCLUDED THAT MAINTENANCE OF A CLEAR DISTINCTION BETWEEN RISK ASSESSMENT AND RISK MANAGEMENT IS CRITICAL TO SOUND

DECISION-MAKING. AS DEFINED IN THE BILL "RISK EVALUATION" WOULD APPEAR TO BE A MAJOR COMPONENT OF THE RISK MANAGEMENT PROCESS, IN THAT IT INVOLVES ATTEMPTS TO ESTABLISH THE "ACCEPTABILITY" OF A GIVEN LEVEL OF RISK. THE BILL, OF COURSE, DEFINES RISK ASSESSMENT TO INCLUDE BOTH "ANALYSIS" AND "EVALUATION."

ALTHOUGH THESE MATTERS OF DEFIITION MAY SEEM RELATIVELY TRIVIAL, I SUGGEST THAT ADOPTION OF THE DEFINITIONS OF RISK ASSESSMENT AND RISK MANAGEMENT RECOMMENDED BY THE NRC WOULD CONTRIBUTE SUBSTANTIALLY TO IMPROVING UNDERSTANDING OF THESE SUBJECTS WITHIN THE CONCERNED SCIENTIFIC AND REGULATORY COMMUNITIES AND BY THE GENERAL PUBLIC. MOREOVER, IT APPEARS THAT FURTHER WORK ON DEFINITIONS MAY BE NEEDED TO CLARIFY THE SPECIFIC REQUIREMENTS OF TITLE I OF THE BILL.

THUS, ALTHOUGH THE DRAFTERS OF THE BILL CLEARLY INTEND THAT THE PROPOSED DEMONSTRATION PROJECTS DEAL WITH RISK ASSESSMENT, WHICH BY THEIR DEFINITIONS INCLUDES BOTH ANALYSIS AND EVALUATION, IT IS NOT CLEAR TO ME THAT THE VERY IMPORTANT DISTINCTION BETWEEN THE SCIENTIFIC ASSESSMENT OF RISKS (AS DEFINED BY NRC) AND THE TYPES OF POLICY ANALYSIS NEEDED TO SUPPORT A RISK MANAGEMENT DECISION IS ADEQUATELY MAINTAINED. THUS, FOR EXAMPLE, SOME OF THE REQUIREMENTS OF THE DEMONSTRATION PROJECT SEEM DIRECTED AT RISK ASSESSMENT, WHILE OTHERS SEEM CONCERNED WITH THE MANAGEMENT PROCESS. UNLESS A CLEAR DISTINCTION IS MAINTAINED BETWEEN THESE TWO SETS OF ACTIVITIES, I suggest the value of the Demonstration Projects will be greatly diminished. I should add that I fully support the specific objectives of the Demonstration projects, and only call for clarification of the content of their various components.

I also note that several aspects of the proposed Demonstration Project have already been studied and reported upon by the NRC Committee. These include means for making the risk assessment activities of the federal agencies more consistent and understandable to the public, and for maintaining the very important distinction between risk assessment and management. I urge that the Demonstration Projects include a requirement that the agencies consider the recommendations of the NRC Committee on these several issues and to take them ito account when undertaking their own studies. And, although I was asked tc comment only on Title I of the Bill, I also note that the NRC Committee examined, at the request of Congress, the desirability of a Central Risk Assessment Board. The Committee concluded that such a Board should be created, but that its activities should not include review of agency risk assessments on specific substances. Rather, it should devote its energies to the development of uniform government-wide guidelines for risk assessment. I hope that the recommendations of the NRC Committee on a Central Risk Assessment Board be considered before completion of the present Bill.

FINALLY, I SHOULD LIKE TO MAKE SOME REMARKS ABOUT WHAT I SEE AS POTENTIALLY THE MOST IMPORTANT REQUIREMENT OF THIS BILL. RISK ASSESSORS ARE BEING ASKED TO PREDICT RISKS BASED ON LIMITED INFORMATION AND INADEQUATE FUNDAMENTAL KNOWLEDGE. ALTHOUGH RISK ASSESSORS CAN CERTAINLY DO MUCH TO IMPROVE THE QUALITY OF THEIR RISK PREDICTIONS, THEY CAN NOT POSSIBLY MAKE THEM MORE ACCURATE WITHOUT A GREAT DEAL MORE KNOWLEDGE THAN WE NOW HAVE. THERE IS ONLY ONE REMEDY FOR THIS STATE-OF-AFFAIRS, AND THAT IS THE DEVELOPMENT OF PROGRAMS OF SCIENTIFIC RESEARCH DESIGNED TO INVESTIGATE THE MAJOR AREAS OF UNCERTANTY IN RISK ASSESSMENT. I AM NOT REFERING HERE TO MORE DATA COLLECTION, BUT TO THE DEVELOPMENT OF NEW RESEARCH METHODS THAT CAN BE USED TO COLLECT THE SPECIFIC TYPES OF DATA NEEDED TO FILL MAJOR GAPS IN KNOWLEDGE. THIS BILL PROVIDES, AT LEAST TO MY KNOWLEDGE, THE FIRST OPPORTUNITY TO LINK IN A SYSTEMATIC MANNER THE NEEDS OF THE RISK ASSESSOR TO THE CAPABILITIES OF THE LABORATORY AND I THINK THIS IS A HIGHLY LAUDABLE GOAL. I ALSO NOTE THAT THE BILL CALLS FOR A RESEARCH AGENDA FOR RISK ASSESSMENT, AS THIS TERM IS CURRENTLY DEFINED IN THE BILL. THIS SUGGESTS THAT THE AGENCIES ALSO INVESTIGATE THE TYPES OF SOCIAL AND POLICY RESEARCH NEEDED TO MAKE BETTER RISK MANAGEMENT DECISIONS; IF THIS IS SO, AND I HOPE IT IS, I SUGGEST MORE EXPLICIT RECOGNITION OF THIS POINT IN THE LANGUAGE OF THE BILL.

ALTHOUGH I HAVE MADE SUGGESTIONS THAT CERTAIN ASPECTS OF THE BILL'S REQUIREMENTS BE MORE CAREFULLY DEFINED, I SHOULD REEMPHASIZE THAT I BELIEVE ITS FUNDAMENTAL OBJECTIVES AND APPROACH ARE VALUABLE ADDITIONS TO THE CONTINUING EFFORT TO IMPROVE BOTH THE SCIENTIFIC AND POLICY ASPECTS OF REGULATORY DECISION-MAKING.

Mr. SCHEUER. Next we have Dr. Peter Huber.

Dr. Huber, can you tell us what your role is at the Supreme Court?

Dr. HUBER. I am a law clerk at the Supreme Court but I am here in my individual capacity.

Mr. SCHEUER. Very good. If you will sum up your testimony in about 8 minutes, we will then have questions for all three of you.

Dr. HUBER. Thank you, Mr. Chairman.

I support H.R. 4192. Risk regulation is the art of making sensible choices. Everything is risky in some degree. The regulator's real challenge is to choose wisely among the alternatives. The goal, of course, is to encourage the safer substitutes and discourage or ban the more hazardous ones. If you don't assess risks and compare risks of available substitutes, risk regulation can make life more dangerous. If you ban one risky product, the market may simply shift to another that is even more risky. Our regulatory agencies have fallen into that trap more than once before.

Let me recite just one example, the FDA's regulation of food additives, which by law is not based on risk assessment and comparison of risks. You can sweeten your coffee with sugar, cyclamates, saccharin, or the new sweetener, aspartame. Cyclamates were banned by the FDA in 1969. Some years ago, when the FDA proposed to ban saccharin, Congress intervened with special legislation to keep the additive on the market. More recently, after long delay, the FDA somewhat grudgingly approved aspartame. No one, to date, has proposed to ban sugar.

The irony of this story is that cyclamates, which were banned, and aspartame, which was approved only after long delays, are probably both safer than saccharin which has been on the market all along. And saccharin, which was almost banned, may well be safer for many consumers than sugar. When the regulator is required to make risk choices like these without the benefit of sound risk assessment and risk comparisons, there is a real chance that regulation will end up making life more dangerous. In Canada, I would inform you, saccharin has been banned and cyclamates are still on the market. One of our two great nations is absolutely crazy. One of us, I won't say which, has banned the safer substitute and continues using the more hazardous one.

If we pick our regulatory targets randomly, we will often do just that: focus regulatory action and efforts on the safer substitutes and shift consumption to more risky alternatives. I am firmly convinced we are already doing this in many areas: pesticide control, electric power production, food safety regulation, drug regulation, and the regulation of new industrial chemicals. This, in my view, is the worst possible thing that risk regulation can do: regulate a safer product out of existence and leave behind only its more hazardous substitutes.

Risk assessment and risk comparisons are the only means, the only means, for systematically avoiding this trap. Risk assessment allows the hazards of risk substitutes to be compared, and comparisons permit the regulator to regulate the more hazardous more strictly. That is the only rational way to steady improvement of our risk environment.

Two difficulties presently stand in the way. First, as has been noted, risk assessment is a difficult and evolving science. H.R. 4192 sensibly attempts to coordinate research and development in this area. Recently, for example, we witnessed the unedifying spectacle of three agencies, OSHA, EPA, and the Consumer Product Safety Commission, passing on the safety of a single chemical, formaldehyde, and reaching quite different conclusions about its safety. Coordinated risk assessment, in cases like this, is obviously efficient, desirable, and educational for all.

The second obstacle to comparative risk assessment under existing law is that the risk universe, from the regulator's point of view, is severely fragmented. Responsibility for risks associated with interchangeable goods or services is often allocated among noninterchangeable agencies. OSHA's authority over occupational hazards, for example, is shared in part with EPA and the NRC. Regulatory authority over different means of pest control is divided between EPA and the Department of Agriculture. EPA and NRC share authority over the hazards of generating electricity. Numerous other examples of overlapping authority of this type can be cited.

H.R. 4192 is a modest attempt to bridge some of these divisions. Better risk assessment and more interagency risk comparisons will help put each agency's risk responsibility in the broader perspective that is needed for prudent, rational regulation.

People who work closely with risk problems, I believe, immediately recognize the need for this bill. Opposition to the bill, on the other hand, appears to be directed at three things that the bill will not, in fact, do.

First, it should be obvious enough, the bill does not require risk agencies to conduct cost-benefit balancing. Each agency's regulatory duties are set out in substantive statutory charters. Some statutes, like TOSCA and FIFRA, require in one form or another cost-benefit balancing. Others, such as OSHA's charter, definitely do not. Nothing in H.R. 4192 will or can change these requirements in any way.

Second, there is no reason that the bill should make it more difficult for agencies to promulgate regulations. I think there is a widespread fear that risk assessment is the first step toward less regulation, less protection of the risk environment. Risk assessment is concededly difficult. The numbers are elusive, uncertain, even when it is fairly clear that there is a real risk out there. The fear is that once careful risk assessment becomes the norm, agencies will be barred from regulating on the basis of more intuitive, qualitative judgments about risk.

Again, I think these fears are entirely groundless. What an agency must, may, or may not do before regulating is already set out in specific statutes already on the books. OSHA's charter, for example, does require risk assessment, or so the Supreme Court has ruled in the benzene decision. The food additive laws definitely do not. Nothing in H.R. 4192 can or does change these requirements.

I am personally convinced that good risk assessment and good risk comparisons would lead to stricter, not more lenient, regulation in several different areas. Some agencies currently underregulate because it is easy for them to overlook or ignore safer alternatives that happen to fall under a different agency's regulatory authority. Overall, risk assessment won't give us less regulation or more regulation. It will simply give us better regulation.

Finally, I do not for one minute believe that this bill will dilute or reallocate existing agency authority. Some fear that risk assessment will give OMB a stranglehold on the risk agencies. When the assessed risks look too low, it is feared that OMB will find it easier to veto regulation. In my view, better risk assessment and more interagency risk comparisons will weaken, not strengthen, OMB's influence. When little is known about the magnitude of a risk, it is easy for OMB to reject a regulation on the grounds that it is unjustified, of unproven necessity, or not in balance with the costs it entails. The more fragmented the risk universe, the easier it is for OMB to divide and conquer, to play off one agency against another. More risk assessment and more interagency coordination will permit better and more comprehensive risk regulation, and that can only strengthen the agencies' hands when undergoing OMB review.

To recapitulate, risk assessment is the art of setting priorities, choosing among substitutes. Because of this, risk assessment by regulatory agencies will proceed whatever this Congress does. The only question is whether it will proceed in the open, thoughtfully, carefully, with dialog among the agencies and guidance from Congress, or in the back rooms, without quality control or accountability to the public, without coordination among the agencies, and without feedback to Congress.

This is an important area. Congress should be leading here, not following. H.R. 4192 is a modest attempt to lead in a sensible direction.

Thank you.

[The prepared statement of Dr. Huber follows:]

TESTIMONY OF PETER W. HUBER
before the
Subcommittee on Natural Resources, Agriculture Research and Environment
of the
House Committee on Science and Technology
May 17, 1984

Thank you for this invitation to testify on Title I of H.R. 4192, the Risk Assessment Research and Development Act.

I am a lawyer and an engineer. In seven years of teaching and conducting research in engineering at M.I.T. I devoted most of my time to technical aspects of risk regulation. As a lawyer I have worked, written, and spoken on the legal and policy dimensions of this same subject. I am currently a law clerk at the United States Supreme Court.

H.R. 4192 is a modest bill. It does not modify existing regulatory statutes, or reallocate agency authority, or put new conditions on regulatory initiatives. It merely informs agencies of Congress's interest in risk assessment, encourages them to develop and use this analytical tool, and calls for more coordination and comparison of risk among various regulatory agencies.

Risk assessment is something we all engage in every day when we cross a busy street, or board a plane, or eat a sandwich. We do it on an intuitive and automatic level. A regulatory agency, acting as the consumer's broker in the risk market, does the same thing on a much broader scale.

Risk assessment is still a primitive art. Various agencies, such as the NRC, OSHA, and EPA, have begun to move risk assessment from the level of alchemy to a real science. Nevertheless, Richard Doll and Richard Peto, two world-renowned epidimiologists, recently wrote the following, in a report on cancer risks commissioned by Congress's Office of Technology Assessment:

> "'[R]isk assessment,' as currently practiced [in cancer research], is so unreliable, suffering not only from random but also probably from large systematic errors of unknown direction and magnitude, that it should definitely be given another name. 'Priority setting' might perhaps be a more honest, although less saleable, name." 66 **J. Nat. Canc. Inst.** 1193, 1216-17 (June 1981).

Risk Assessment under Existing Statutes

Most risk statutes already permit or require regulation to be based on the assessment and comparison of risks. Examples include the Toxic Substances Control Act, The Occupational Safety and Health Act, the Clean Water Act, and the Federal Insecticide, Fungicide, and Rodenticide Act. Some statutes, such as the food additive provisions of the Food, Drug and Cosmetic Act, do not.

H.R. 4192 would not change any of these laws. It would only encourage the various agencies that administer them to pool their expertise on the subject of risk assessment, and to compare the different types of risk that they regulate. It would also give some feedback to Congress on an important tool of risk regulation that is already widely used by the agencies.

Coordinating risk assessment efforts in different agencies will make possible faster and more reliable regulation. Recently, for example, three federal agencies--EPA, OSHA, and the Consumer Product Safety Commission--made separate (and ultimately different) risk decisions about a single chemical--formaldehyde. Cases like this arise often. Radiation risks are regulated by at least three agencies--NRC, EPA, and the FDA. Transportation risks are regulated by several different offices such as the FAA and NHSTA. Food risks are regulated by both the FDA and the Department of Agriculture. When different agencies share responsibility for overlapping risks coordinated risk assessment permits regulation to be developed more efficiently, and to be focussed more clearly on the worst hazards of our environment.

Risk Assessment and Risk Choices

Making sensible choices is what risk regulation is all about. Everything is risky in some degree. The regulator's challenge is to choose wisely among the alternatives. The hope is to encourage safer substitutes and discourage or ban more hazardous ones. Every regulator knows that the search for absolute safety is illusory. We can only strive to push things steadily in a safer direction.

But regulators can make wise choices only if they start with (1) reliable risk assessment, and (2) the opportunity to examine the full range of choices available. Without risk assessment a regulator cannot rank choices in terms of their relative hazard. And without a broad focus on the full range of alternatives, the regulator may overlook safer alternatives and therefore accept unnecessary hazards.

If you don't assess risks accurately, and compare the risks of available substitutes, risk regulation can make life more dangerous. Our regulatory agencies have fallen into that trap more than once before.

Let me start with a familiar example from an agency--the FDA--whose statutory charter largely forbids basing regulatory decisions regarding food additives on risk assessment and risk comparisons. (H.R. 4192 would not, of course, cure the problems illustrated by this example, because the bill does not change any existing statutory mandates.)

There are at least four ways to sweeten your coffee--sugar, cyclamates, saccharin, and aspartame or "nutrasweet." Cyclamates were banned by the FDA in the late 1960s. Some years ago, when the FDA proposed to ban saccharin, Congress passed special legislation to keep the additive on the market while the National Academy of Sciences assessed the sweetener's risks and possible benefits. Congress recognized that the risks of substitutes to saccharin--such as sugar--might be worse than the risks of saccharin. In the end, as you know, special legislation was passed and saccharin was not banned. More recently, after long delays, the FDA approved a new low-calorie sweetener--aspartame, or "nutrasweet."

The irony in this story is that cyclamates--which have been banned--and aspartame--which was only approved after years of delay--are probably both safer than saccharin--which was marketed without restriction all along. And saccharin--which was almost banned--may well be safer (at least for diabetics and those who are overweight) than sugar. When the regulator is required to make risk choices like these without risk assessment and risk comparisons, there is a real chance that regulation will end up making life more dangerous for all. Canada, for example, has done exactly the opposite of what we have--it has banned saccharin, but permits the continued marketing of cyclamates. One of us, in short, has banned the safer product and continues to use the more hazardous one.

If we pick our regulatory targets randomly, half the time we will focus regulatory efforts on the safer substitute, and end up driving consumption toward more risky alternatives. We are almost certainly already doing this in areas such as pesticide control, electric power production, food additives, and drug regulation. Yet surely the worst possible thing that risk regulation do is to regulate a safer product out of existence, and leave behind only its more hazardous substitutes.

Risk assessment and risk comparisons are the only means for avoiding this trap. Risk assessment allows the riskiness of substitutes to be compared. And risk comparisons permit the regulator to regulate the more hazardous more strictly. That is the only route to steady improvement of our risk environment.

Inter-Agency Risk Comparisons

Risk assessment is the first step in ranking risks intelligently. The second is making sure that we compare the full range of available choices before deciding that a particular risk is tolerable--or intolerable.

The risk universe, from the regulator's point of view, is severely fragmented. Responsibility for risks associated with interchangeable goods or services is often allocated among several agencies.[1] And within a single agency statutory requirements for old risks are often different from those for new risks.[2] For example:

* OSHA's authority over occupational hazards is divided into safety and health channels, and is shared with EPA (insofar as occupational hazards come from certain toxins, e.g. pesticides) and the NRC (for some radiation-related employment hazards). There is little coordination among the agencies on target levels of job safety.

* There are at least three means of controlling pests on crops--manmade pesticides, "nature's" pesticides synthesized naturally by crop varieties that have been carefully bred to be pest-resistant, and biological controls such as insect parasites, predators, and pathogens. But regulatory authority over these different means of control, all of which present environmental risks of one type or another, is divided between EPA and the Department of Agriculture, impeding rational regulatory trade-offs among these alternatives. In practice, because of these regulatory divisions, we have accepted too much risk from artificial chemicals, too little from alternative means of control.

* EPA's and NRC's respective regulations of the risks of electric power generation (EPA for coal- and oil-fired generation, NRC for nuclear) are not adequately structured around comparisons of the relative risks of different generating technologies.

* Numerous statutes call for stricter regulation of new sources of risk than of old ones. The result has been tolerance of too much old risk, and too little new. Under the Toxic Substances Control Act, for example, most of EPA's regulatory efforts have been directed at new chemicals, of which there are relatively few, while too little attention has been given to hazardous old chemicals, of which there are many.

H.R. 4192 is a modest attempt to bridge some of these divisions. More and better risk assessment, and more inter-agency risk comparisons, will greatly assist in putting each agency's risk responsibilities in a broader perspective.

---

[1] See P. Huber, Risk Markets, **Regulation** -- (March/April 1984) (forthcoming).

[2] See P. Huber, Exorcists vs. Gatekeepers in Risk Regulation, **Regulation** 23 (November/December 1983); P. Huber, The Old-New Division in Risk Regulation, 69 **Virginia Law Rev.** 1025 (1983).

What H.R. 4192 will not do.

What H.R. 4192 will do is plain enough. It will prompt agencies to develop, coordinate, and disseminate their knowledge about risk assessment, and report back to Congress on the subject. This is a research and education bill, nothing more. Some agencies have made much progress with risk assessment, but others have not. And all suffer from too much insularity, too intense a focus on the limited segment of the risk universe that happens to fall on their regulatory turf.

People who work with risk every day immediately recognize the need for this bill. Opposition to the bill, on the other hand, appears to be directed at three things that in fact the bill will not do.

1. H.R. 4192 does not require risk agencies to conduct cost-benefit balancing.

Each agency's regulatory duties are set out in its substantive statutory charters. Some statutes, such as TOSCA and FIFRA require, in some form or another, cost-benefit balancing. Others, such as the OSH Act, definitely forbid it. Nothing in H.R. 4192 will change these requirements in any way.

2. H.R. 4192 will not make it more difficult for agencies to promulgate new regulations.

Some people fear that risk assessment is the first step toward less regulation and protection of the risk environment. Risk assessment is difficult--the numbers are often elusive and uncertain, even when it is fairly clear that a serious risk is at hand. The fear is that once risk assessment becomes the norm, agencies will be barred from regulating on the basis of more intuitive judgments about risk. People with these fears have in mind, perhaps, the Supreme Court's Benzene decision, in which the Court overturned an OSHA regulation precisely because the Agency had failed to assess risk before promulgating the new standard.

These fears are groundless. Again, what an agency must, may, or may not do before regulating is already set out in specific substantive risk statutes. The OSH Act, for example, does require risk assessment, or so the Supreme Court has ruled. The food additive law of the Food Drug and Cosmetic Act plainly does not. Nothing in H.R. 4192 will change these requirements. Burdens of proof concerning risk are set by laws that are already on the books. H.R. 4192 does not change them.

Moreover, it seems plain to me that more and better risk assessment would, at least in some areas, lead to tighter, not looser, regulation. Risk assessment, and inter-agency risk-comparisons, will assist agencies in the better administration of their existing statutory mandates, administration more consistent original Congressional intent. In some areas regulation may be relaxed, but in others it will become stricter. Risk assessment and risk comparison are tools for better regulation, nothing more.

They may sometimes shift regulatory emphasis, but there is no reason why they should decrease the overall level of regulatory activity.

3. H.R. 4192 will not dilute or reallocate existing agency authority.

Some fear that risk assessment gives OMB a stranglehold on risk agencies. When the assessed risks look too low, it is feared that OMB will find it easier to veto regulation.

In my view, better risk assessment, and more inter-agency risk comparisons, will weaken, not strengthen, OMB's influence. The more fragmented the risk universe, the easier it is for OMB to divide and conquer. When little is known about the magnitude of the risk, it is easy for OMB to reject a regulation as one of unproven necessity, or to attack it as unjustified in light of its likely cost. And when no risk comparisons have been made, it is easy for OMB to reject a regulation on the ground that substitute risks under the authority of another agency have not been considered. More risk assessment, and more inter-agency coordination, will permit better and more comprehensive risk regulation. And that can only strengthen the agencies' hands when undergoing OMB review. This bill takes nothing away from existing agency authority, and gives no new authority to OMB. In the long run, educating agencies on the science of risk assessment can only diminish OMB's power.

Conclusion

Since everything is risky in some degree, risk regulation is a matter of choice among substitutes, a matter of setting priorities. Because of this, risk assessment by regulatory agencies will proceed, whatever Congress does. Agencies cannot regulate everything instantly; risk assessment in one form or another is what they use to set priorities and to determine the appropriate stringency of regulation. The only question is whether risk assessment will proceed in the open, thoughtfully and carefully, with dialogue among agencies and guidance from Congress, or in the backrooms, without quality control or accountability to the public, without coordination among the agencies, and without feedback to Congress.

This bill pushes things gently in a positive direction. It stimulates more work by agencies on risk assessment. It promotes dialogue among the various agencies conducting this type of analysis. It encourages comparative risk assessment and public education. It sets the stage for further work in this area. And it will give Congress much-needed feedback on what actually happens once a substantive risk statute leaves Capitol Hill and is handed over to an administrative agency for implementation.

The choice for this Congress is whether to encourage and facilitate progress in this area, or to leave it to the agencies to muddle along, as they have heretofore. There is still much to be learned, and much to be done in risk regulation--as the recent Agent Orange and Nevada A-bomb test cases have demonstrated. Congress should be leading in this area, not following. H.R. 4192 is a modest effort to lead in a sound direction.

EXORCISTS VS. GATEKEEPERS IN RISK REGULATION

Peter Huber

REGULATING HEALTH AND SAFETY hazards is an endeavor fraught with two risks of its own. Regulation may impede risk-reducing change, freezing us into a hazardous present when a safer future beckons. Worse still, as with the Hydra's head, when one risk is removed, two others often grow up in its place.

It is commonplace to observe that risk is ubiquitous and inescapable. Every insurance company knows that life is growing safer, but the public is firmly convinced that living is becoming ever more hazardous. Congress, understandably enough, has been more interested in the opinion polls than in the actuarial tables. A bountiful crop of federal health and safety regulation, most of it of recent harvest, reflects the popular concern.

The risks of foods and drugs are subject to intricate and comprehensive legislation. The adverse health effects of air, water, and land pollution are the province of four major and equally complex environmental statutes. The risks of transporting people or hazardous cargoes are strictly regulated. The hazards of electric power generation are regulated by the Environmental Protection Agency (EPA) if the fuel is coal or oil, by the Nuclear Regulatory Commission (NRC) if the fuel is nuclear. Consumer products have their very own safety commission; occupational safety and health its own administration (OSHA). Among the myriad other special purpose risk statutes are those devoted to household poisons, mine safety, natural gas pipelines, flammable fabrics, and lead paint.

I argue here that federal regulation of health and safety is not only a major obstacle to technological transformation and innovation but also often aggravates the hazards it is supposed to avoid.

Two Goals, Two Procedures

Risk regulation has two overarching goals—goals that are distinct and often contradictory. It aims, on the one hand, to reduce the "old" risks of our environment. I am referring here to risks that accompany such familiar activities as driving a car, or digging for coal, or stepping

---

Peter Huber, a Supreme Court law clerk, holds a doctorate in mechanical engineering and a law degree.

REGULATION, NOVEMBER/DECEMBER 1983

out for a breath of air. On the other hand, risk regulation seeks to impede technological changes that threaten to introduce "new" hazards into our lives. I have in mind here risks associated with the likes of nuclear power, artificial food additives, and new toxic chemicals.

These two goals—the control of old risks and the exclusion of new ones—lead to profoundly different legislative commitments. The first is made when Congress wakes up one day to discover that things somewhere out there are intolerably hazardous. The resulting "something ought'a be done" laws are transformational. They demand a change in the established order—clean-up programs, if you will. The second kind of commitment is the child of a Panglossian dream, in which Congress sees the ominous unknown encroaching on this safest-of-all-possible worlds. So the "don't let it happen" laws are exclusionary. They demand protection of the presumptively safe status quo—like anti-littering programs.

The two different legislative objectives spawn two quite different regulatory procedures: "standard setting" and "screening." Under a standard-setting regime of regulation, reserved for old risks, you go about your business until Washington, in its own good time, comes to you and tells you how to do it better. OSHA is an example of a standard-setting agency. "Screening," which applies to new hazards, is regulation by advance licensing. *Before* undertaking a new venture, you go to Washington to ask for permission. The Food and Drug Administration (FDA) is a screening agency. OSHA and the FDA regulate chemically similar toxins, but use fundamentally different regulatory tools.

> **These two goals [of risk regulation]—the control of old risks and the exclusion of new ones—lead to . . . . two quite different regulatory procedures: "standard setting" and "screening."**

Standard setting is initiated by the regulatory agency. If a standard-setting agency promulgates a standard based on inadequate scientific evidence of the underlying risk, the standard will be thrown out by the courts. Screening places the burden of initiating the regulatory process on the regulatee. A screening agency can survive a judicial challenge by proving its complete ignorance about the hazard involved. It is up to the would-be licensee, the person trying to pass through the screening system, to prove that the screened product is acceptable.

> **Standard-setting agencies aspire for a safer world: they exorcise the devils we know. Screening agencies . . . protect the universe of risk from deterioration: they act as guardians at the gate. . . .**

Standard setting is an incremental, transformational approach. Standard-setting agencies aspire for a safer world: they exorcise the devils we know. Screening agencies, on the other hand, serve to protect the universe of risk from deterioration; they act as guardians at the gate, making yes-no kinds of decisions, protecting us from the ominous unknown.

Congress generally decrees that standards shall be set for old products, old sources of risk, and that screening will be used to regulate new products, new risks. Standard setting is reserved for our "familiar killers"—risks that society has come to tolerate before the decision to regulate is reached. Screening regulates new risks that loom on the horizon—risks that threaten to undermine the perceived safety of the status quo.

Thus, we set standards for cars, but screen aircraft. We set standards to control the old hazards of burning coal, but screen new nuclear power plants. Under the Toxic Substances Control Act (TOSCA), EPA is supposed to screen all major new productions of "new" chemicals, but is directed merely to set standards for the production and handling of old ones. EPA screens new pesticides but for the most part leaves the old ones alone. Numerous other examples could be cited. Of course, some statutes, like the Clean Air Act, combine elements of standard setting (in establishing ambient standards) and screening (to set individual new source emission limits). But overall, the old/new line falls remarkably close to the standard-setting/screening division.

Indeed, Congress exerts itself mightily to preserve the division. The FDA, my basic example of a screening agency, regulates both old food hazards and new ones. And OSHA, my basic standard-setting agency, regulates both new work-place risks and old ones. But it turns out that the old-new regulatory division is carefully codified at a second level, within each agency's statutory charter.

The FDA's regulation of foods, for example, is rigidly subdivided between natural foods (very "old"), food additives ("new"), and a curious group of substances "generally recognized as safe" (GRAS). GRAS substances are substances that were "old" and therefore nonthreatening when the FDA polled the scientific community on the matter in the late 1950s. TOSCA similarly divides the regulatory universe of toxic chemicals between old chemicals —in this case chemicals in significant use before 1973—and new ones. The Clean Air Act calls for the screening of new major sources of pollution, but only sets standards for old ones. The Federal Water Pollution Control Act contemplates more stringent regulation of new emitters than of old ones. New pesticides are regulated more severely than the old ones. Again, numerous other examples can be found.

Process and Reality

So what? Who cares if the procedures for regulating old and new risks are different? The answer, I think, is found in the words of Alfred North Whitehead: "The process is itself the actuality." There is a difference between Mohammed going to the mountain and the mountain coming to Mohammed. Procedures *do* make a difference.

The Supreme Court's decision in *Industrial Union Department* v. *American Petroleum Institute* (1980)—the benzene case—was about procedures. OSHA had come to realize that regulating occupational exposures to carcinogens through standard setting is difficult and time-consuming. So it set about promulgating its own, in-house Delaney Amendment. Under its proposed carcinogen policy, no employer could introduce into a work place chemicals that had been found to be carcinogenic in test animals. OSHA would make no assessment of actual risk to humans; it would be up to employers to prove, if they could, that non-zero occupational exposures to animal carcinogens were safe. Through the magic of the *Federal Register* OSHA would turn itself into a screening agency, shifting burdens of proof from the agency to the regulatee. OSHA's benzene standard, though promulgated just before the agency's official carcinogen policy, reflected the evolving philosophy.

But the Supreme Court would not go along. It ruled, in effect, that OSHA was constituted as a standard-setting agency and would have to behave like one. It is up to OSHA to demonstrate that its standards will mitigate a "significant risk," not up to employers to show that their work places are "safe."

For a standard-setting agency this result made perfect sense. For a screening agency it would have been extraordinary. When the FDA declines to license a new food additive and thereby effectively bans the additive, the agency is not required to show that the additive poses a significant risk. The FDA may simply insist that it is ignorant, that safety has not been proven by the regulatee to the agency's satisfaction. The same is true for the NRC when it declines to grant an operating license to a new plant, or for the FAA when it holds up on licensing a new aircraft, or for the EPA when it declines to license a new pesticide, or for any other screening agency, when the information available does not support an affirmative finding of acceptability.

The different procedures for regulating old and new risks—standard setting and screening —can thus have profoundly different substantive consequences. Screening, first of all, regulates at the "strict" margin of scientific uncertainty, standard setting regulates at the "lenient" margin. A screening system admits only the "acceptably safe," while a standard-setting system excludes only the "unacceptably hazardous." There is often a wide gap in between those two criteria.

Screening systems also place the cost of acquiring the information needed for regulation on the regulatee; standard-setting systems place that cost on the agency. This makes all the difference when the product or process targeted for regulation is only marginally profitable. A pesticide manufacturer may have to spend $20 million on tests needed for licensing. Even if a pesticide is completely safe, it will never even be submitted for review if the manufacturer stands to make only $19 million from its sale.

The cost problem also impels screening systems to favor big-ticket products and operations—a broad spectrum drug, a new pesticide that will kill everything from aphids to dung beetles, the largest nuclear power plants. As in most other ventures, there are economies of scale in paying the price of being screened. Securing regulatory approval of a single 1000 MW power plant will certainly cost less than securing approval of two 500 MW plants. So our nuclear plants tend to get bigger and bigger, our pesticides less and less specific.

. . . there are economies of scale in paying the price of being screened. . . . So our nuclear plants tend to get bigger and bigger, our pesticides less and less specific.

Standard-setting systems, in contrast, tend to place the greatest burdens on the largest regulatory targets because it is there that the standard-setting agency can have the biggest impact. A small generator of an unusual type of risk is often beneath the standard-setting agency's attention.

Another component of cost is delay. Under a screening system it is the regulatee who bears the risk and cost of regulatory delay. Delay postpones the return on R&D costs and allows the clock to tick on crucial patents. In standard setting, delay postpones the cost of compliance until an agency acts—which may mean forever, especially if you have a good lawyer litigating avidly on your side.

The final and most important difference between standard setting and screening—that is, between the regulation of old and new risks—is found in the statutory criteria for regulation. Standard-setting statutes almost always limit in some manner the *costs* that a regulatory scheme may impose on regulatees. Screening statutes rarely contain analogous cost-conscious provisions.

I could march through the kinds of opaque statutory provisions I have in mind, but this is an exercise for footnoters, and moreover an exercise I have recently completed elsewhere ("The Old-New Division in Risk Regulation," in *University of Virginia Law Review*, September 1983). Moreover, Congress is always embarrassed and therefore somewhat reticent when a crass consideration like money must be injected into a risk statute. Let me instead offer just one example.

In the famous cotton-dust case, *American Textile Manufacturers Institute, Inc.* v. *Donovan* (1981), the magic statutory term was "feasible." OSHA standards may be strict but must be "feasible." The Supreme Court rejected a claim by textile manufacturers that OSHA's new cotton-dust standard should be invalidated because it was not grounded on a cost-benefit analysis. "Feasible," the Court said, does not mean justified in formal cost-benefit terms. But what is at least equally striking about the case is what "feasible" *does* mean. The Court found the term to require that "the industry as a whole will not be threatened by the capital requirements of the regulation." The Court therefore approved a standard that, according to OSHA's own estimates, will permit a continuing incidence of byssinosis among 15 percent of textile workers. Any stricter standard would not be "feasible" because it would cost the industry too much.

At least when compared with the typical screening statute, OSHA's statutory mandate is strikingly cost-conscious. The NRC, by way of contrast, is certainly not required, and quite possibly not even permitted, to consider economic impacts when it withholds the Diablo Canyon license, or for that matter when it freezes out all future development of nuclear power. The same is true for the FDA, when it declines to license a new food additive, and for many other screening agencies. For those screening agencies that are required to weigh costs and benefits, burdens of proof usually remain with the regulatees, so that uncertainties about cost or benefit are consistently chalked up against the proposed new product or process.

Origin of the Double Standard

Old risks subject to standards are systematically treated more leniently than new risks that are screened. What accounts for the double standard?

Some suggest that informational problems are at the root of the division. We set standards for old risks because they are familiar and therefore well understood. We screen new hazards because we know less about them. Yet those in the business know that informational problems are pervasive even for hazards as old as asbestos and wood fires. Others have suggested that the psychological dimension of risk accounts for the old-new division. "Rare catastrophes" provoke different legislative responses than "common killers." Again I am skeptical. Rare catastrophes are caused by old sources of risk every bit as much as by new ones. Somewhat more convincing is Robert Crandall's suggestion that the old-new division results from the raw politics of competition between the industrially old, politically powerful Frost Belt and the industrially new, less powerful Sun Belt (*Controlling Industrial Pollution*, 1983).

Though all of these factors undoubtedly play some role, I am convinced that the old-new division is primarily attributable to something much more pedestrian. Congress thinks that it is much more expensive to regulate old risks than new ones. That belief is understandable enough. Cleaning up the risk environment requires direct cash outlays. Regulated industries rebel at these transition costs; consumers are dismayed to lose products to which they have become habituated. People are usually of the view that it is better that things be settled than that they be settled right.

In contrast, excluding new risky products or activities seems relatively painless. Manufacturers do not have to readjust production processes, consumers do not have to change established patterns of consumption. The only cost that *is* incurred by the regulation of new types of risk is the price society pays whenever it decides not to do something—a lost opportunity cost. Congress, it seems plain, systematically judges this type of cost to be relatively small or at least obscure.

Congress's belief that it is cheaper to exclude one unit of new risk than to neutralize one unit of old risk is both plainly wrong and readily understandable. It is plainly wrong because lost opportunity costs are not uniformly negligible. To cite just one example, uniquely therapeutic drugs are often licensed in this country years after they are approved elsewhere. The people who lose the opportunity to be treated in the interim definitely pay a very real price. More generally, this misapprehension about costs reflects the alarming view that there is little to be lost in obstructing technological and scientific change.

Congress's belief that it is cheaper to exclude one unit of new risk than to neutralize one unit of old risk. . . . reflects the alarming view that there is little to be lost in obstructing technological and scientific change.

But Congress's view about costs is also readily understandable because legislators care more about *political* costs than economic ones. Old risks derive from established technology and their regulation presents unwelcome production and consumption choices. Old risks have identifiable and self-aware constituencies. In contrast, the regulation of new risks attracts much less political heat. Under a rigid, predictable screening system industry loses little—it just steers clear of the field. Consumers lose, of course, but—here's the political kicker—they don't know it.

Formula for Regression

To sum up, we have established a systemic preference for old sources of hazard and a systemic bias against new sources of risk. Imbue this system with the widely held belief that life is too dangerous, encourage it with vocal demands that life be made safer, and you have a formula for inexorable technological regression.

First, everything is risky in some degree.

Second, we decide to go after risks aggressively.

Third, we determine that the cheap way to avoid risk is to exclude new risks, to cut back on our most novel products and processes.

Finally, we set up a bifurcated regulatory process, one that is far more risk-averse and far less cost-conscious when it regulates new risks than when it regulates old ones. The older, the more entrenched the status quo, the slower we are to regulate it strictly. The newer, the more speculative, the more innovative the regulatory target, the more likely we are to take a firm, no-risk, exclusionary stand.

Two things, I believe, have brought us to where we are now. First, there has been a change in the national mood. Somewhere along the way we lost our taste for technological exploration and adventure. Ours seems to be what Arthur Kantrowitz, an engineer and scientist, dubbed the era of "neo-Malthusianism." We share, he believes, a profound belief that "mankind cannot manage the great power that it is able to unleash." Second, we have progressively changed the way in which we regulate risk, and that has greatly affected the conclusions we reach about the acceptability of risk.

There was a day when risks were regulated only *after* the accident, after the bodies had fallen, through liability rules administered by the courts. The incentive not to create a risk was that if the risk was an unreasonable one, you might end up paying compensation, and perhaps punitive damages, to the person you injured.

This retrospective regulatory system was cumbersome, it diverted too much to the lawyers, it placed on injured persons an often insurmountable burden of proving causation, it was erratic and unpredictable. But it had one large advantage. To recover in the courts you had to prove *harm*. A cardinal rule of tort litigation is that the courts do not compensate exposure to risk—"the neighbors your dog doesn't bite"; they compensate those who are bitten. This means, first, that risks have to be real before they are regulated by the courts, and second, that the "acceptability" of a risk is evaluated at a time when the social utility of the risk-creating activity is known.

But risk regulation is becoming an increasingly prospective business. Agency standard setting is the first step in this direction. Once a pattern of unacceptable harm becomes clear, an agency intervenes to mandate across-the-board correction. Like a court, the standard-setting agency must have evidence of harm before it regulates. But unlike a court, the standard-setting agency regulates wholesale, not retail, once that evidence is found. Both the suspect risk-creators and the proven harm-causers are regulated uniformly.

Screening moves regulation yet another step forward in time. Screening regulation occurs before any pattern of harm is apparent or predictable. It is grounded on some generalized anxiety about risk in a particular area. A screening agency regulates not on the basis of proven harm, but on the basis of unproven safety. This is the ultimate step in prospective intervention—you cannot move regulation any earlier.

There are two central problems with pushing regulation earlier and earlier, as we seem determined to do. First, the earlier we regulate, the harder it is to assess the *benefits* of the product or activity regulated. A century ago people agitated to ban vaccination. It seems unlikely that the eventual eradication of smallpox figured prominently in the debate. More recently, we have witnessed attempts to curtail significantly experiments in genetic engineering. Who can begin to assess what benefits we would forgo if such research were in fact halted?

Second, the earlier we regulate, the harder it is to evaluate *risk* accurately. Of course, we regulate early precisely because we do not want to count bodies later. But without bodies it is very easy to overestimate risk, especially when the national mood is receptive to claims of new and lurid risk. Indeed, early regulation can become something of a self-fulfilling prophecy. We start with unfocused anxiety about a product and set up a strict regulatory regime. The public infers from that action that the product is especially dangerous. Enthusiasm for strict regulation grows, impelling the politically responsive agency to regulate even more strictly. And of course the public infers from the stricter regulatory regime that there is even more danger out there than originally thought.

The paradox of risk regulation is that too much of it makes life more dangerous. Not just more expensive, not just less convenient, but more dangerous.

Which brings me full circle. The paradox of risk regulation is that too much of it makes life more dangerous. Not just more expensive, not just less convenient, but *more dangerous*. The introduction of new, safer products is slowed; safer (but not perfectly safe) products recently introduced to the market are driven out, and consumption shifts back to the old and common killers, which are entrenched and therefore too costly to regulate seriously.

Proposals for Change

What is to be done? The most popular reform proposal these days seems to be risk-benefit balancing—monetize both the injuries and the benefits of the hazardous activity and then bring in chartered accountants to balance the books. I fear the proposal is up against insuperable political obstacles. Moreover, if you propose cost-benefit balancing, I ask, by whom? The last thing a regulatee whose product is to be screened should want is an additional requirement that *it* prove the acceptability of the product in risk-benefit terms.

There are less ambitious reforms in the air. The patent term extension bill looks as if it will pass Congress next year. It would stop the clock from ticking on patents while regulatory review is in progress, and so remove at least one of the costs of being screened. And the Orphan Drug Act, enacted a few months ago, streamlines and subsidizes the licensing of new drugs that treat very rare diseases. Until now, it often did not pay to try to push these so-called orphan drugs through the system.

Other promising proposals would standardize the screening process in various fields. For example, if nuclear plants are ever built again in this country, the NRC will undoubtedly push for an extremely standard plant that can be approved once and then built by all. Again, the purpose would be to cut down on the staggering transaction costs associated with screening regulation. Finally, it is also occasionally proposed to force some cost-consciousness on to screening agencies. The proposal usually takes the form of a threshold risk criterion. Screening agencies would be required to establish the likelihood of a given degree of harm before deciding to ban an established product from the marketplace.

I believe there is one politically feasible possibility for more far-reaching reform. One of the most common, and most profoundly fallacious assumptions made in the risk-regulation trade is that new products and processes generally add to the risk burden of our environment. In fact, most new products do not "add to," they "substitute for." Yet under most existing regulatory statutes, the agency is clearly and flatly prohibited from comparing the risks of a new product with the risks of the old products for which it will substitute.

Examples abound. The artificial sweetener saccharin, although thought to present some risk, has been kept legal by special act of Congress. After ten years of delay, the FDA recently approved a new dietetic sweetener called aspartame. But the agency had to establish that aspartame met an objective level of safety; it could not lawfully have approved aspartame simply by establishing that aspartame was safer than saccharin.

The NRC, and its myriad consultants and contractors, have become extremely expert at estimating nuclear risks. Understandably, nearly all their efforts are directed at estimating risks of nuclear power. EPA devotes vastly fewer resources to assessing the risks of the nonnuclear alternatives that it regulates—coal power, for example. Neither agency is encouraged, nor perhaps even permitted, to base its regulatory decisions on a comparison of the risks presented by the alternative generating technologies.

. . . banning one risky product may decrease societal risk or may increase it. It depends entirely on what is left behind. . . . In recognition of this painful reality, risk agencies should be restructured around natural "risk markets."

Our regulatory system must find a way to recognize that most things in life are substitutes, not additions. The uncomfortable truth, widely ignored, is that banning one risky product may decrease societal risk, or it may increase it. It depends entirely on what is left behind.

In recognition of this painful reality, risk agencies should be restructured around natural "risk markets." The hazards of all sources of electric power should be placed under one regulatory umbrella. We should discard the artificial regulatory divisions between "natural foods," food additives, and "GRAS" substances. In the area of occupational safety and health, the regulator must recognize that strict regulation of safer jobs tends to drive workers toward more hazardous ones. We should abandon the artificial divisions between old and new drugs, old and new emitters of air pollutants, old and new pesticides, old and new chemicals, at least when the new target for regulation promises to substitute for an old product or process. Functional substitutes should be regulated within a single agency according to more or less uniform decisional criteria.

Reorganizing our risk agencies around natural risk markets would have some obvious advantages.

First, a comparative approach to risk regulation can operate in perfect harmony with our reluctance to regulate old risks precipitately. If we are determined to proceed with circumspection in our regulation of old risks, those risks provide the perfect benchmark for a comparative system.

Comparative regulation would also make risk regulation more credible. It is always much easier to compare risks than to make determinations of absolute safety. Critics might complain less about the overfeeding of rats if the data simply showed one group of live and healthy aspartame-fed rats and another group of dead or ailing saccharin-fed rats.

Comparative regulation might also promote desirable comparison between the so-called technologically enhanced risks and the all-natural hazards of our environment. Some state legislatures, for example, have passed nuclear waste disposal laws that, if applied literally, outlaw the excretion and disposal of human waste, which, like everything else on this middle earth, is mildly radioactive. Comparative risk regulation might help to deter such idiocies.

Finally, comparative regulation would help to avert the most intolerable of all possible risk regulations—regulations that aggravate the hazard they are supposed to mitigate. Again, historical examples of the problem are easy to come by; I shall recite only three.

- Cyclamates have been banned in this country, while saccharin has not. Canada has followed exactly the opposite course. One of us has banned the safer product and continues to use the more hazardous. Comparative regulation would impel the FDA to determine whether it might be we who have followed that irrational course. (Today, the FDA is not legally empowered to inquire how the risks of cyclamates compare with those of saccharin, once it has made the threshold determination that both are carcinogenic.)
- The high wall between the NRC's risk decisions and EPA's allows one agency—I will not venture to say which one—to pile increasingly strict regulations on the safer branch of the industry, with the effect of driving production toward the more dangerous. A single Electric Power Safety Administration might be less prone to accept that type of regression.
- Some time ago the FDA banned bottles made of acrylonitrile because small amounts of the carcinogenic plastic leach into the drink. But an "all-natural" *glass* bottle containing soda under pressure has much in common with a hand grenade, with an unexpected defect in the glass playing the role of the firing pin. Before the advent of plastic bottles, exploding glass bottles caused tens of thousands of injuries in this country every year. Plastic bottles have been a great setback for the trial lawyers of America. Yet at no time was the FDA legally empowered to ask how the risks of acrylonitrile bottles compare with those of glass bottles.

The Reaction

The idea of comparing interchangeable sources of risk before deciding which to regulate, or how strictly, seems so simple, so obviously reasonable. It was with some surprise that I discovered that this proposal encounters vehement and vocal opposition. The criticism comes in subtle forms but it has two basic refrains: risks are unmeasurable and risks are incommensurable.

Unmeasurability. This has become quite a crusade. The arguments sound like this. Don't trust the experts. Don't believe any estimates of risk probabilities. Regulate according to maximum conceivable harm, ignore the likelihood of harm. Expand the definition of risk— I quote from one prominent commentator's recently published suggestion—to include all "sociopolitical, biological and geophysical conditions."

This is, of course, intellectual rubbish that can be answered in short order. If risks are unmeasurable, then risk regulation is an utterly futile endeavor. You cannot rationally control what you cannot measure.

Incommensurability. This is a more popular, more credible, and more pernicious attack on comparative risk regulation. It runs something like this. Risks in the nature of carcinogens are special—the public demands particularly strict cancer control. Occupational hazards associated with the production of a hazardous product have attendant benefits (they provide jobs) and so should be treated differently; in effect, labor-intensive risks are more tolerable than capital-intensive risks. Risk regulation tends to reallocate wealth from one group to another; we must attend to the distributional and allocative effects of regulation. Rare catastrophes are different from common but localized hazards; we must regulate the two classes of risk according to different criteria. Some risk decisions have international consequences; we must regulate so as to avoid exporting hazardous technologies. Some hazardous technologies are more susceptible to terrorism and sabotage; regardless of the actual magnitude of risk, these technologies require especially strict treatment.

This incommensurability lament is so varied, and so amorphous, that a short response is difficult to articulate. Suffice it to say that for a governmental agency, well-meaning but with finite resources, this kind of fragmentation of the risk universe is a recipe for utter paralysis. And keep in mind that regulatory paralysis under our regulatory system as presently structured means that new risks will be excluded and old ones accepted.

Despite their weaknesses, the unmeasurability/incommensurability attacks on comparative risk regulation receive a great deal of press. The ascendant belief seems to be that comparing risks is an impossible, fraudulent, or fanciful practice, designed to obscure the issues, avoid the difficult questions, narrow the range of choices—in short, designed to implement what has been denounced as the tyranny of the experts. For my part, I do not for a moment believe that comparative risk regulation would usher in a "tyranny" of any description. And a comparative approach, with a single focus on aggregate risk, is the only one that comes close to being capable of rational implementation by our less than omniscient regulators.

The opposition to comparing risks is, I believe, a perverse reaction to one unshakable and (to many) unacceptable reality: in spite of popular misconceptions on the subject, life is in fact growing safer, not more dangerous. New technologies, new products, new processes are almost uniformly safer than the old ones they replace. Many fear, perhaps with good reason, that a comparative approach to risk regulation will lead to regulatory choices that favor new technologies over old ones, capital-intensive technologies over labor-intensive technologies, and large-scale, centralized projects over small-scale decentralized ones. There may be strong and good political and sociological reasons for resisting any or all of these trends. Those reasons, if they exist, should be aired in the appropriate political arenas. They should not, however, concern regulatory agencies whose task—already difficult enough—must be to monitor and improve our risk environment. If we insist on asking our risk agencies to do too much, they will do too little. Measuring and comparing risks is no small task. Risk-regulating agencies should not be concerned with promoting jobs, allocating wealth, or tending to the psychological health of the nation. ■

. . . life is in fact growing safer, not more dangerous. New technologies, new products, new processes, are almost uniformly safer than the old ones they replace.

Selected Readings

On risk regulation and innovation in general, see: Henry G. Grabowski and John M. Vernon, *The Impact of Regulation on Industrial Innovation* (Washington, D.C.: National Academy of Sciences, 1979); Peter Huber, "The Old-New Division in Risk Regulation," 69 *Virginia Law Review* (September 1983); and Richard B. Stewart, "Regulation, Innovation, and Administrative Law: A Conceptual Framework," 69 *California Law Review* (September 1981).

On comparative risk in the fields of energy, pharmaceuticals, and pesticides, see respectively: Herbert Inhaber, "Risk with Energy from Conventional Sources," 203 *Science* (February 23, 1979); J.E.S. Parker, "Regulating Pharmaceutical Innovation: An Economist's View," *Food Drug Cosmetic Law Journal* (1977); and William Tucker, "Of Mites and Men," *Harper's*, August 1978.

From the forthcoming Regulation magazine, copyright 1984 by the American Enterprise Institute. Not to be reprinted without permission or quoted without credit.

THE SACRED TEXT of Lilliput declared that eggs should be broken only at the "convenient" end, and the Littlenders and Bigenders fought passionately to determine which end that was. Today we know, of course, that what comes out of the shell is all that really matters. Or do we?

There has been much talk about tradable pollution permits and exchange in risk-abatement duties but remarkably little action. Under the Clean Air Act, for example, it remains the law that a polluter may not trade pollution abatement duties with anyone but itself, even though air quality does not depend on whose chimney emits the smoke. The polluter that invests in a modern, cleaner-than-required plant may not agree to relieve some other polluter of an offsetting regulatory burden—even if the two are eager to make the deal. Most other health and safety statutes are equally hostile to an even exchange in risk.

The Visible Hands

Other examples abound. Trade in risk between risk "producers" and risk "consumers" is most rigidly forbidden. A manufacturer may not sell a cheap lawn mower without a blade guard, even if he prints "Buyer Beware!" all over the blade. Your employment contract might state that you assume the risk of on-the-job injuries in exchange for a "risk premium" in your wages, but your employer would remain liable for your injuries nonetheless. An airline may not invite each passenger to choose between a life vest under the seat and more space for carry-on luggage. Regulatory agencies often ban such trades prospectively; when they have not, the courts uniformly refuse to make the trades binding after the risk is realized. The freedom to contract, in other words, ends abruptly at disclaimers of risk liability and waivers of risk-related rights to sue. Express agreements to transfer risks fall to the doctrine of "unconscionability," and when contracts are silent agreements *not* to transfer risk are found under the guise of "implied warranties."

Risk trading among risk producers is similarly banned. A nuclear power plant operator may not increase emissions of radiation from its modern plant by paying for offsetting radiation reductions from antiquated X-ray facilities operated by local dentists. An automaker may not trade off exhaust emissions from one of its models against those from another, even if its "corporate fleet" meets aggregate emission limits, nor may it trade two bumpers and a collapsible steering column for an air bag, even if the bag costs less and saves more lives. An employ-

---

Peter Huber, a Supreme Court law clerk, holds a doctorate in mechanical engineering and a law degree.

er may not trade higher cotton dust levels for safer weaving looms even if the current looms cause more injuries than the dust. A seller of diet soda may not substitute cyclamates for saccharin even if cyclamates are safer.

The obstacles to this type of intra- or inter-producer risk trading are codified in the various risk statutes. Within a single regulatory statute, as in the Clean Air Act, risk producers are given individual duties of risk mitigation that may not be bought or sold. Polluters must not only limit emissions—a duty potentially tradable with other polluters—but must also install specific types of pollution control technology—a duty that is inherently untransferable. Indeed, regulatory authority itself is often structured around the specific types of technology used rather than the nature of the risks created. Radiation is radiation, but dental X-ray machines (which radiate a good bit) are on the Food and Drug Administration's turf, nuclear power plants (which radiate little) on the Nuclear Regulatory Commission's. Administrative insularity takes care of the rest. We recently witnessed the unedifying spectacle of three agencies—the Environmental Protection Agency, the Occupational Safety and Health Administration, and the Consumer Product Safety Commission—reaching quite different conclusions about the safety of a single chemical, formaldehyde. Even when hazards of one type appear to be addressed in a single statute—such as the Toxic Substances Control Act—jurisdictional overlaps with other agencies prevent any effective inter-producer risk trade-offs.

Finally, trading off risks among goods that are interchangeable to consumers is also strongly discouraged. Since the regulator acts *in loco parentis* for the consumer in deciding how much and what kind of risk we consume, the barriers to this kind of trading are again found between the agencies. Completely interchangeable goods or services are often overseen by entirely separate regulatory agencies. No regulatory trade-off between the public risks of generating electricity by burning coal or "burning" uranium is permitted. The risks of one job are not deemed tolerable simply because they are lower than the risks of another job held by employees of similar skills. The risks of traveling by bus are not weighed—at least at the regulatory level—against the risks of traveling by car. When goods of one type—food, or pesticides, say—happen to be placed under a single regulatory umbrella, countless finer distinctions again preclude risk trade-offs. New artificial food additives are regulated more strictly than those that were already in use in the 1950s, which in turn are regulated more strictly than "natural" toxins. Occupational health risks must be regulated more strictly than safety risks, or so the Supreme Court suggested in its 1981 *Cotton Dust* decision.

The Hazards of Inalienable Risk

The ban on trading "safety," like a ban on trading any other good, results in too little production of safety, and at inflated cost. Going it alone always entails double toil and double trouble.

The ban on trading "safety," like a ban on trading any other good, results in too little production of safety. . . .

The trading ban, which can be seen as a ban on competition in the production of safety, makes safety unnecessarily expensive. Trading locates, unerringly and quickly, the person able to supply the most safety at the least cost (as Maloney and Yandle show in "Bubbles and Efficiency," *Regulation*, May/June 1980). Central planning and distribution of risk abatement duties do not. OSHA's asbestos standard, for example, saves lives at an estimated cost of $200,000 per life while its benzene standard costs $18 million. Highway maintenance, new guard rails, and so on cost $50,000 per life saved, air bags about $300,000. Lowering radiation from X-ray machines would cost $3,600 per life saved, compared with about $1 billion for better disposal of civilian nuclear waste. If trading were allowed, such vastly different prices for such very similar benefits would not persist.

For similar reasons the trading ban results in the production of too little safety. The stringency of regulation is usually limited by economic feasibility. If risk could be avoided more cheaply, stricter regulation would thus be possible. So long as health hazards in the work place must be regulated more strictly than safety hazards, we will produce, relatively speaking, too much health and too little safety—and, in the aggregate, too many dead or injured employees. If carcinogenic pesticides are regulated more strictly than their poisonous (but noncarcinogenic) counterparts there will be few cancers but a more than offsetting number of other poisonings.

Finally, the ban on risk trade-offs by regulators can push consumption toward more hazardous products. I have discussed this at some length in *Regulation*'s pages before ("Exorcists vs. Gatekeepers in Risk Regulation," November/December 1983). Suffice it to say here that when interchangeable products are regulated by noninterchangeable agencies the less dangerous product often ends up regulated more strictly than the safer. This inevitably leads to a regressive shift in consumption. A "theory of the second best" operates in risk markets just as in economic ones; the second safest regime to universal and uniform risk regulation is not necessarily patchy regulation applied only here and there.

Beyond Property

In light of these substantial costs, why does our regulatory system so categorically reject risk trading? The first part of the answer lies in regulatory history.

Risk legislation is mostly reactive. There was a day when the law not only permitted but assumed that risk producers and risk consumers bargained for and traded risk burdens. An employee would "assume the risk" of doing his job, a buyer of a consumer product factored risk into the price unless some other arrangement was expressly agreed to, a person acquiring property near a polluter's "came to the nuisance" and so would not be heard to complain later about the smoke. Risk producers thus could and frequently did enter into binding agreements that shifted risks to consumers. Indeed, for a long time such transactions were thought to be constitutionally protected. State law could not, for example, infringe on an employee's "freedom" to work dangerously long hours, or so the Supreme Court declared in a notorious 1905 decision, *Lochner* v. *New York*.

Times changed. Today the prevailing view is that risk consumers are not competent risk traders. They are presumed to lack either the information needed to negotiate fair risk trades, or the organization needed to make collective decisions when dealing with "public" risks such as those caused by pollution. The regulator, acting as the consumer's agent in the risk market, can overcome both problems. Free trade in risk is therefore replaced by individual, inalienable entitlements to certain levels of safety, obtained from risk producers through the intercession of regulatory agencies. The agencies strive to secure for each of us an entitlement to "safe and healthful working conditions," food free of "any poisonous or deleterious substance which may render it injurious to health," drugs that are "safe and effective," consumer products that pose no "unreasonable risks of injury," and so on. That the individual consumer might wish to trade away such entitlements is a possibility that plays no part in the regulatory scheme. A person may no more sell his entitlement to safety than he may sell his right to vote or to receive food stamps. Given what came before, the inalienability of risk entitlements was probably inevitable.

But words pay no debts, and it takes more than a declaration of entitlement (inalienable or otherwise) to make the world safe. For every new right to safety a new duty to mitigate risk must be created. Unsurprisingly, these duties are created measure for measure with the new entitlements. X is given a new, inalienable entitlement to cleaner air, and Y is charged with a new, untransferable duty to reduce his emissions. It is all pleasantly symmetric.

And half of it is extravagantly inflexible. Although there may be good reasons to forbid risk trading by the individual consumer, they certainly provide no justification at all for imposing a ban on trading among risk producers. Worse still, the ban on risk trading among agencies often means that the agencies end up working actively against consumers' collective safety interests.

Inalienability and Equal Protection

Perhaps it was all just a mistake. We so rarely think in terms of trading "bads" that it is difficult to recognize, at first, that there are important benefits in allowing risk producers to do so. But I suspect the ban on risk trading has deeper roots.

The simpler objections to risk trading are easily rebutted. Some protest that a trade in social duties is immoral. No one may trade away a duty to sit on a jury or to serve in the army, and risk abatement is thought to belong in the same class. But a moral disdain for trade should crumble when the consequence of no trading is higher risk for all.

Others fear that trade in risk will erode the entitlement to safety. Before long, risk consumers might have to *pay* for safety entitlements, and this would be intolerable. But the right to trade a duty need not determine who bears the cost of the corresponding entitlement. Moreover, it is charmingly naive to think that because something is inalienable it is also free. Consumers obviously pay dearly for the benefit even if Congress announces each new safety entitlement with a pious proclamation of inalienability.

Still others link the inalienability of risk duties to the convenience of the regulator. Uniform, rigid, hardware-oriented duties are easier to enforce than shifting rights and duties traded in a dynamic market. This justification for untransferable risk-control duties has merit, but it too ultimately fails to persuade. Regulatory inconvenience is merely one among many elements of regulatory cost. Regulatees can be made to shoulder increased administrative expenses along with the other costs of regulation and will readily do so if the new expenses are more than offset by the cost savings that lie in risk trade.

So how *does* one explain the persistent opposition to the trading ban? The rigid inalienability of risk rights and risk duties seems to be grounded in a wishfully egalitarian new conception of "equal protection."

From the regulatees' point of view, the main objective is to avoid bearing any disproportionate share of the regulatory burdens. The one regulatory burden that all risk producers find utterly intolerable is the burden not shared by their competitors. As Robert Crandall points out in his *Controlling Industrial Pollution* (1983), a regulatory system built around specific, technology-based standards ensures absolutely equal treatment of classes of risk producers. Thus, under the Clean Air Act, new or modified pollution sources must be fitted with technology that ensures the "lowest achievable emission rates," while in clean areas the "best available control technology" is required. This certainly ensures equal treatment of new polluters, but the cost is high—large, unnecessary capital investment in areas where protection of air quality requires none. The irony is that if the equal treatment pact were found anywhere but in a federal statute, it would flagrantly violate the antitrust laws because it eliminates all incentives for polluters to compete in the production of safety.

Risk consumers may oppose trading among risk producers for somewhat different reasons. Some fear that trading may retard risk abatement by giving risk producers vested rights in current levels of risk generation. But steady risk abatement need not exclude trade. The rate at which current rights to pollute are devalued by regulatory fiat need not depend on who currently holds those rights. Indeed, the economic savings realized through trade would permit devaluation all the more swiftly. More commonly, the insistence on inalienability is linked to the fear of "hot spots." If the right to create risk were transferable, a food-carcinogen monopolist might corner the market and put all his risks in girl scout cookies. And then where would we all be? Risk consumers reflexively assume that their equal protection from predatory risk producers is ensured only by inalienable duties in risk producers. Inalienability is our anti-monopolization strategy for risk, with the ban on trading extending not just to monopoly-creating trades but to every exchange, no matter how small.

The Black Market in Risk

And it is a strategy that is entirely unnecessary, unless we also believe in the eccentric consumer. If we all consume about the same mix of foods it should not matter much where we get our food carcinogens. But the regulator worries about the consumer whose only real pleasure is cookies, who consumes his own quota and yours and mine as well. So the regulator insists on regulating retail, not wholesale, and attempts to supervise each unit of risk production, each incident of risk consumption, drawing countless fine distinctions between different types of risks and the different demographic groups destined to bear them. The hope is to spread each type of risk uniformly, so that the burden may be shared equally by all. Indeed, risk spreading becomes an affirmative regulatory strategy, spawning taller (but more polluting) smokestacks, decentralized (but more dangerous) electric power generation, distributed (but in the aggregate more harmful) occupational hazards.

Equal protection from risk nevertheless remains an entirely unrealizable aspiration. Though we might like the acid rain to fall equally on the just and the unjust, it never will.

First, equal treatment of *both* the producers and consumers of risk is impossible. If the risk producers tend to concentrate in particular geographic areas (as industrial polluters do), equal treatment for them translates inexorably into unequal treatment of the risk consumers. Notice that under the Clean Air Act it is equality for polluters—not for air-breathers—that has prevailed. Unless the uniformly risky products and services of producers end up uniformly distributed, unequal distribution of risk among consumers is inevitable.

Second, and more important, risk producers and risk consumers are remarkably agile and persistent in their efforts to trade. The result is a domestic black market in risk as vibrant as the market for blue jeans in Red Square. Risk generators, for example, craft elaborate schemes to deal only with those whose risk-related demands are modest. A manufacturer of mutagenic chemicals may decline to hire women in child-bearing years—unless they undergo sterilization. (Why won't a mere promise not to become pregnant suffice? Because the surgical contract, unlike a paper one, cannot be nullified by the courts.) Some industries relocate to places, here or abroad, where the risk demands of the general public are lower. Some employers may try to shift risk burdens to employees simply by using genetic screening to avoid hiring employees most susceptible to certain types of risk. As a result, markets subject to less strict risk regulation thrive, while their more strictly regulated counterparts wither.

The usual domestic response is, unsurprisingly, to create new equality-enhancing entitlements: a right to be hired regardless of procreative preference or genetic constitution, a ban on exporting hazardous products, safety entitlements vested in foreign workers, and so on. But new schemes for trading can usually be invented faster than new entitlements can be codified, and the black market in risk continues to flourish. The waves simply will not subside at King Canute's command.

Risk consumers, too, find ways to escape the cocoon of inalienable safety entitlements. Work-place safety standards go unenforced because employees decline to trade their entitlement to safety for the entitlement to unemployment compensation. Perverse consumers insist on buying the cheaper product or service, even when the low price reflects less strict regulation. Cyclamates can be purchased in Canada, laetrile in Mexico. And inevitably there are some destined to choose the most dangerous car *and* job *and* television *and* sleepwear, and they, of course, do not end up "equally protected." Some unlucky consumer always manages to stand up just as the slings and arrows of outrageous fortune come whizzing by.

Fortune, in fact, may be the key. Wealth has an unexpectedly important impact in determining how much risk we bear. A statistical study has shown that after removing the effects of age, race, sex, education, and other possibly extraneous factors, a 1 percent increase in income reduces mortality by about 0.05 percent. Put in proper perspective, this is a large number. For a forty-five-year-old man working in manufacturing, a 15 percent increase in income has about the same risk-reducing value as eliminating *all* hazards—every one of them—from his work place.[*]

This strong link between wealth and a risk-free environment should be very sobering. First, equal protection may be entirely unattainable without equal wealth. It appears that money is the ultimate transferrable safety permit, and money is far from equally distributed. Second, risk seems to remain highly tradable, despite our efforts to freeze it in place. How else do the wealthy manage to end up with so little? Finally, if wealth is so important in the risk market, perhaps we should be less quick to accept unnecessarily expensive risk control strategies. Cheaper regulation *could* mean more money not just for the producers but also for the bearers of risk. And money, not a gas mask or an organic garden, seems to be the key to the safer kingdom.

---

[*] The −0.05 elasticity is from Jack Hadley and Anthony Osei, "Does Income Affect Mortality?" *Medical Care*, vol. 20, no. 9 (September 1982), p. 901. The calculation for the manufacturing employee runs as follows. For forty-five-year-old men, annual total mortality is about one in a hundred (Edmund Crouch and Richard Wilson, *Risk/Benefit Analysis*, Ballinger Publishing Company, 1982, p. 4). This means that a 15 percent increase in income will decrease the man's annual risk of dying by about 0.05 × 0.01 × 15 = 0.008 percent. If the man works in manufacturing, his annual risk of dying a job-related death is about the same (see ibid., p. 178). Of course safety is worth relatively more to a younger man or to a person in an initially more hazardous occupation, and relatively less to an older man or one in an already safe occupation. But the numbers I have chosen are not atypical.

Risk Markets

Which brings me to risk "markets." Trade in risk, like trade in anything else, can generate wealth and so increase the production of safety. Increased safety for all lies in more risk trading, and in larger markets.

I do not propose a return to bargaining between the individual consumer and his butcher, baker, or candlestick maker, over the risks that food, jobs, or consumer products will contain. There are obviously good reasons—reasons quite consistent with reducing risk efficiently—to retain the regulator as the consumer's broker in the risk market. I am interested, instead, in the large volume of risk trading that could be conducted entirely among the experts, to the benefit of all.

There are, to start with, natural markets for risk producers. Although there are innumerable sources of risk, there are relatively few types of risk that are physiologically distinct. In the jargon of the risk business, the human body is a bubble too (turned inside out, I suppose, since we are interested in what goes in, not what comes out). The risk of radiation exposure may not belong in the same market as the risk of fire, but (to repeat) radiation *is* radiation, whether exposure comes from a dental X-ray or a nuclear power plant or a granite building. As a matter of fact most of the public's exposure to radiation comes from the X-rays, not the nukes. If dentists and nuclear-power-plant operators were allowed to trade, our radiation burden would go down substantially, and everyone would save money to boot. Likewise, chemical carcinogens may not be interchangeable with acute conventional poisons, but the benzene you breathe at the factory *does* have the same effect as the benzene you breathe when filling your tank at the corner station. Physiologically indistinguishable risks, in short, belong in the same risk markets.

Who should be allowed to trade in such markets? Under appropriate regulatory supervision—by a radiation review commission, a carcinogen control board, an office of traumatic injuries, and so forth—producers of a single type of physical hazard should be allowed to trade. To make sure that consumers shared some of the resulting benefits, one might require better than even trades: each time a risk-abatement duty is transferred it could also be slightly inflated, so that the new bearer of the duty has to do a little better than the old one. Trading would still occur, and life would get safer faster. If the factory and the local gas station were to agree on a shared benzene output lower than their present joint emissions, your body-bubble would certainly benefit. And I find something very attractive about permitting the operators of Three Mile Island to vent small amounts of radioactive gas in exchange for a more than offsetting upgrade in the X-ray facilities of local dentists. If you remain worried about fairly distributing risk burdens, keep in mind that though we all must breathe the same air dental X-rays are aimed disproportionately often at children's heads.

Risk markets can also be built around interchangeable *goods* rather than interchangeable "bads." The consumer is faced with choices between a diet soda containing aspartame or one with saccharin, between electricity generated from coal or from nuclear fuel. There is no more sense in regulating separately the several risk components of the cookie, the car, or the electric power grid, than in distinguishing two chimneys in the same industrial plant. Even the cookie freak or the all-electric householder cannot be helped by the fragmented regulation.

In thinking about consumer risk markets we must remember that it is the regulator who is to act as surrogate shopper for the risk consumer. Consumers buy goods despite their attendant risks, not because of them, and the common assumption is that the consumer does not know or care enough to take risk into account. Ideally, then, we want the regulator to pick and choose among risky alternatives in the same way as an omniscient consumer might.

And here we run into the major difficulty. Under present law the individual regulator rarely has the same range of choice as the consumer he is supposed to protect.

- Jobs of similar skills in similar geographic areas may well be interchangeable to employees, and therefore belong in the same risk market. Low-skill jobs may not be interchangeable with their high-skill counterparts, but factory jobs and agricultural work perhaps are. Yet OSHA's authority over occupational hazards is divided into safety and health channels, and is, moreover, shared with EPA (insofar as occupational hazards come from certain toxins—for example, pesticides) and with the NRC (for some radiation-related employment hazards). There is little coordination among the agencies on target levels of job safety.
- There are at least three means of controlling pests on crops—man-made pesticides, "nature's" pesticides synthesized by carefully bred pest-resistant strains of crops, and biological controls such as insect parasites, predators, and pathogens. But regulatory authority over these different means of control, all of which entail environmental risks of one type or another, is divided between EPA and the Department of Agriculture, impeding rational regulatory tradeoffs among these alternatives.
- Transportation by car, bus, and subway may be reasonably interchangeable, within the city at least, but the risks of the different technologies are regulated entirely separately. The very occasional subway accident evokes cries for costly improvements in safety, while the extent to which the associated price increases encourage commuters to drive is never addressed. Flying is thirty times safer than driving, yet the FAA continues to tighten its safety standards for short-haul jets. What effect this has on the cost of flying—and how many people therefore make the trip by car instead—is not known.
- To the consumer of electric power it makes no difference—insofar as the focus is on the good itself—how the power is generated. Yet EPA's and NRC's risk regulations are not structured around comparisons of the relative risks of different generating technologies. The current trend has been gross underregulation of coal power and extreme overregulation of nuclear, thus substantially increasing the risk of consuming electricity.
- Most foods are more or less interchangeable and so belong in a single risk market. But the FDA's statutory charter distinguishes between "natural" and "artificial" toxins, carcinogens and noncarcinogens, new food additives and old ones. The agency routinely accepts a substantial "natural" hazard in preference to a less significant but "artificial" one that might displace it.

Consumers, it must be recognized, actively choose among interchangeable goods in markets such as these, paying little heed (or so our regulatory system assumes) to the risk consequences of their choices. If the regulator's range of choice is not equally broad, things are dangerously wrong. And getting more dangerous. A regulator with tunnel vision may dutifully proceed to ban the dangerous product that falls on his particular piece of the regulatory turf, while a colleague decides not to place restrictions on the more hazardous substitute that he has to deal with. This regulatory failure to operate in natural risk markets, comparing risks and making the trade-offs that a rational, well-informed consumer would make, means that risk regulation is often entirely counterproductive.

Opponents of risk trading systems will often concede as much. But they insist that objectives other than risk minimization are at stake—spreading the costs of accidents, striving for more equitable distribution of risk burdens, and reallocating wealth. Risk regulation's honeycomb of inalienable rights and duties, we are assured, guarantees—or at least promotes—equal protection of risk consumers.

Experience teaches otherwise. The distribution of risk, as reflected in the mortality tables, remains highly uneven. The wealthy and the well-educated bear little risk; the poor and the uneducated, a great deal more. The regulator's aspiration for "equal protection" fails to yield a uniform distribution of risk, and instead insulates risk producers from all competition in the production of safety. Worse still, it fuels a tragically wasteful, incessant bickering about the distribution of risk duties and entitlements. Distributional objectives divert us from what should be the central issue—the aggregate degree and cost of risk abatement. While we debate about which particular chimney may emit the smoke the air remains dirty, killing in eastern urban areas an estimated 50,000 people a year. The wealthy, of course, move to the suburbs. ■

Mr. SCHEUER. Congressman Ray McGrath.

Mr. MCGRATH. No questions, Mr. Chairman.

Mr. SCHEUER. Congressman Ritter of Pennsylvania.

Mr. RITTER. I thank the chairman.

If you are wondering where I was during my absence, I sprinted down to 2123 to provide a statement on smoking. We have recently developed a smoking bill in the Health Subcommittee in Energy and Commerce, and I was certainly not about to lose the opportunity to deal with that number one avoidable hazard that we all have to face.

I have a question for Dr. Ashford. Dr. Ashford and I are old friends on this. We go back, I think, to the first set of hearings back in 1979 or 1980. I would like to compliment him on his consistency. He is as negative today as he was then. However, it is certainly a valid viewpoint.

I would like to ask you, Dr. Ashford, whether you do conduct risk assessments at the MIT Center for Policy Alternatives.

Dr. ASHFORD. I indicated in my testimony that we are, in fact, at the cutting edge of developing methodologies in that area. We do, indeed, do that kind of risk assessment, and it would be in my financial interest as director of the center to support this bill because I would get more work. We do it for the Federal agencies. We do it for industry that would ask us to do this work, OSHA, EPA, the Consumer Product Safety Commission. We would do it for unions who might ask us to look at something.

We are, as you know, a university, and we believe we are doing risk assessment motivated from an examination of the facts. We believe in the science, Don. The problem is, I think this bill unintentionally, very likely, will give political control of what should remain a scientific exercise. That is where my quarrel with it is. It is not that we shouldn't do risk assessment, encourage it, and improve the validity, because we are committed intellectually to that endeavor.

Mr. RITTER. Yes. Let me ask you if it is appropriate to do risk assessment on items of Federal regulation in a university, why is it not appropriate to do risk assessment on items of Federal regulation in the science offices and laboratories of the Federal agencies?

Dr. ASHFORD. Who said it was inappropriate in the Federal agencies?

Mr. RITTER. Then, since it is not an inappropriate thing to do both in the Federal agencies and in the universities, why when we take a legislative view to sponsor some greater coordination, some interagency cooperation, some seeking out of consistency, when we seem to have the backing of the National Academy of Sciences, people who have been involved very strongly in developing the report, we seem to have the backing of virtually the entire risk assessment community which has supported these concepts as evolved not only in their own institutions but in the Federal Government as well, why do you as the director of the center for policy alternatives take such issue with all of your colleagues?

Dr. ASHFORD. I don't know that I do take issue with my colleagues. I think you can't indicate that because my colleagues support risk assessment that they would support this bill. That is a different matter.

Mr. **Ritter**. Let me just point out if I might that virtually the entire science oriented community that is dealing with risk assessment is in favor of this bill.

Dr. **Ashford**. We talk to different people. That is not my observation.

Mr. **Ritter**. Well, I can provide you with the list of people who, after 5 years of dealing with the subject, you can bet that whoever is for it has already communicated with me and whoever is against it has already communicated with me.

Dr. **Ashford**. Well, my views are not conditioned on a popularity contest. Let me answer the question as you asked it. First, let me say that I think that had the legislation or—had there been a legislative initiative to strengthen, let's say, and I am not at all quarterbacking for NIHS, but had the NIH budget had a line item in it that said the National Institute for Environmental Health Sciences and the National Institute for Occupational Safety and Health and the National Cancer Institute shall devote so many million to coordinating and developing and improving the scientific base for risk assessment, I would have supported such an initiative.

I am glad you asked your question, because the straight answer is that I see political manipulation of the evaluation of the kind of risk assessment work that is going to be coming out of these agencies through the mechanism of the report that is being anticipated, I know and you know that you can choose scientists to do risk evaluations where it will come out larger or smaller in terms of how things look. The methodologies—I made this point in my direct testimony which you had to miss—the point is that the risk analysis——

Mr. **Ritter**. By the way, if I had had that testimony before this morning, I probably would have had time to go over it in detail.

Dr. **Ashford**. But I made the statement in 1980 in prior testimony, Don. It is the same statement, and that is that risk analysis technologies and methodologies are value-laden in themselves. Whether you choose a linear extrapolation mode for cancer or a Bryant model or whatever model you choose, it will get you within three orders of magnitude a larger or smaller number. So, one can choose the scientist to get the risk assessment number that you want. When OMB and OSTP might be calling the shots as to who is annointed as the scientific group of people who are doing the good research as opposed to the bad research, I balk.

Mr. **Ritter**. You know, it is interesting, in your testimony you——

Mr. **Scheuer**. Will my colleague yield just briefly?

Mr. **Ritter**. Yes.

Mr. **Scheuer**. Can you give us any specific examples of what you are talking about? I think that you are hinting, at least, but very obliquely, at sort of manipulation of the scientific process.

Dr. **Ashford**. I will be more than oblique.

Mr. **Scheuer**. Where is that taking place?

Dr. **Ashford**. In my article which I submit for the record on the way three Federal agencies handled the formaldehyde problem, the political manipulation because of present times of scientists and scientific information in OSHA and EPA is blatantly clear. For example, OSHA fired Peter Infante who was their scientist on the risk assessment of formaldehyde.

The second example is OSTP's so-called policy on cancer which was drafted by John Toddhunter and is a disgrace in scientific terms. That is what I am talking about, and the evidence is clear about political manipulation.

Mr. RITTER. Excuse me, if I might regain my time, because I think the gentleman is making some extraordinarily political—I think the gentleman is——

Mr. SCHEUER. Now, wait a minute, Don, please. You can have all the time you want to ask him further questions. Let him finish the specifics, because I think it is important for us to know. In the history of risk assessment as a tool, what do we learn from it? Please give us all the specifics that come to mind in this connection, and then Congressman Ritter will have the chance to ask any further questions he wishes.

Dr. ASHFORD. The history, on the one hand, of risk assessment in the Federal agencies has been one of steady improvement, that is, where the scientists were actually asked, go and try to find out how big a problem we actually have, they have done a credible job. The history, as you asked the question, of the use of this information or abuse of this information are the instances that I am concerned about.

For example, in the EPA, the whole risk assessment exercise on formaldehyde was virtually thrown aside by the then Administrator of the Office of Toxic Substances and his own interpretation substituted for those of the scientists who had devoted 2 or 3 years to that topic. In fact, the personnel were so disgusted that they left the Agency. You can delve into the history, and in the Harvard Environmental Law Review article on which we spent 2 years in the making, we have documented the history of the misuse of that data.

There are too many chances for this kind of abuse. Let me turn the question on its head. Why are you so opposed to having a nonregulatory agency like NIEHS essentially through the mechanism of an NIH funding enhancement do the science? Why must it be so tied to the political process?

Mr. RITTER. Frankly, I would like to answer that question. I have no problem with NIH playing a role in developing research in this area. Absolutely not.

You know, you made the comment that you would be better off if this bill would be passed because this bill means more money for risk assessment. But we are not putting more money for risk assessment in this. Your later comment that we should have a new budget, we should have a new expenditure, we are already doing a great amount of this.

Let me get to some of these so-called manipulations. Our bill does not enter into these kinds of political decisions. You can do anything you want with data. My bill attempts to provide a greater range of it, a greater scope, a greater evolutionary process within the Federal Government. If somebody wants to take your numbers—you know, you tend to say that that which is not done at the Center for Policy Alternatives or that which is not Nicholas Ashford's is wrong and that which doesn't take your view. Nicholas, you are known in the community for not exactly being the quiet, middle of the road, objective risk assessment type. You have vast political judgments of your own that you bring to your testimony today, that you bring to the Center for Policy Alternatives over the years, and I happen to know full well that this is the—you are as political a figure in the area of risk assessment as anyone that I have been associated with in the 5 years that I have dealt with the subject.

I have to just come out and say that because that is the truth. If you want to take a poll of the people in the field, take a poll.

I have some questions that——

Dr. ASHFORD. I would like to respond. I think I am due the courtesy of a response.

I agree with everything you said except that the risk assessment that I do is not objective. I hope my politics are clear. I hope my commentary is interpreted as political. I mean it to be political. This is a political exercise. However, no one, to my knowledge, has ever accused my Center of performing a risk assessment to fit a client, to distort the science, and I think you may want to reconsider your remarks when you state that the risk assessment and science which we perform is in any way distorted, because I think you won't find support for that statement.

Mr. RITTER. My comment was that you are a highly politicized individual and that you are talking about the politics of your opposition, the people you don't like. OMB is the evil guy and OSTP is the evil guy. I don't see it that way. I see there are different forces, but I want to go on the record by saying that your work may be accepted by the scientific community and there is the work itself, but you as an individual are highly political. You have deeply held political views, and I think that should be put on the record in this hearing.

I would like to ask Dr. Huber how he feels about some of Dr. Ashford's comments about how this bill would be taking risk assessment into the political realm.

Dr. HUBER. If it does that, I think Congress better find out about it, because the vast majority of risk statutes on the books already require or permit risk assessment and it is actively used by agencies. If this is the ultimate in political manipulation, Congress had better find out about it as quickly as possible and pursue these studies, because all regulation is currently based, or virtually all regulation of risk is currently based on risk assessment of some description. So, the Congress best bet if you want to have statutes you have written and passed enforced properly, your best bet is to encourage development in this area.

Mr. SCHEUER. If the gentleman will yield, this isn't the first time we have heard about the manipulation of risk assessment processes. This very subcommittee has taken an active role in an absolutely bipartisan or nonpartisan way. We did have a good look at the use of science advisory committees by the EPA last year, and we found out that they did have hit lists and that they did manipulate the use of science advisory committees. We did find out that the EPA did instruct one of their regional offices in Chicago, IL, as to what language they should put in a report on dioxin, on the dioxin that they were studying emanating from the Tittabawassee River.

So, the whole question of political interference with a scientific process both within and without the administrative agencies is not a question that is unknown to us.

Dr. Ashford might tell us something about his knowledge of the use and abuse of the science advisory boards, briefly, if you care to.

Dr. ASHFORD. Well, in fact, I submitted for the record the article I had written on the history of the use of technical advisory committees by EPA and OSHA where the history is clear. EPA had a hit list of people who were no longer acceptable on that science advisory board, replaced almost entirely the 60-member science advisory board members, and, in my view, as I have analyzed, in violation of the Federal Advisory Committee Act requiring a fair balance. The kind of victimization of personal people with denial of contracts and so forth is legend.

I think we cannot continue with the naive view of any piece of legislation, however well intended, to improve the science. I just want to go on the record that I am for an improved competency in the agencies, an improved coordination of their risk assessment activities, a comparison where possible, Peter, of the kind of risks—and you and I agree that risk markets in a particular area ought to be looked at on a comparative basis. You know, there is not as much disagreement as you may think. I simply get to the heart of the matter which is, I don't like the opportunity to further politically manipulate science. I believe science ought to be done in the open and free of political interference with full discussion, and I don't think this bill gets you there.

Mr. RITTER. Mr. Chairman.

Mr. SCHEUER. Yes, Mr. Ritter.

Mr. RITTER. Mr. Chairman, I don't disagree with what he is saying. However, I would submit that my bill takes the risk assessment and comparison out into the open. It stimulates a greater level of public interaction. If there are abuses in the past, it sure didn't happen because of my bill. The fact is that some of this stuff is taking place because of behind closed doors and it is always too technical for the people or the people can't really understand this—the people have got to know. And one of the ways the people will know is if we openly deal with this problem, if we come not just in the halls of the National Academy of Sciences, not just at MIT's Center for Policy Alternatives, but the media has to have a greater acquaintance with hazards and the perspective on hazards.

This is one step in opening the process, in building a kind of greater understanding of risk assessment, and stimulating greater concern with emerging techniques. I don't think it should be stuck in MIT's Center for Policy Alternatives or NIH or any Federal agency. I think it should be brought out in the open. This is a mechanism to do that without hiding one thing. In a sense, I agree with a lot of the things that you are saying, and I am saying that my bill does that, and you are saying that my bill does the opposite. It could be that there are some judgmental differences between us, but I think on the substance and on the content we are saying the same thing.

Mr. SCHEUER. Dr. Rodricks, we haven't heard very much from you in this rather frenetic interchange. Let me start off with a question just in the hopes that I can stimulate you as another member of the panel to speak for a few minutes. Do you think that some perhaps independent scientific organization like the National Academy of Science perhaps might be better suited than OMB for identifying and developing new research methods that have been referred to?

Dr. RODRICKS. I haven't, frankly, given that question a lot of thought in my consideration of the bill, but generally I think I would agree with Dr. Ashford on that point. As an overseer of what I define as risk assessment, at least, NIH or the National Academy, I think, would be the most suitable place.

My confusion arises because it seems to me that risk assessment as defined in the bill encompasses more activity than I would ordinarily include under risk assessment, as I said in my testimony. To the extent that it involves questions of risk acceptance and the like, it seems to me a bit to overstep what the bill should be examining most closely. That is my only real reservation about the bill.

Mr. SCHEUER. Congressman, let me ask you, we are discussing OMB as a reasonable but potential designee by the President to do the risk assessment. As I understand it, on acid rain, OMB did that risk assessment, and it was OMB that has put the lid on Mr. Ruckelshaus on the basis of their risk assessment that we don't know enough to do anything about acid rain. What do you say to the question of what the likely designated entity will be by the President? What agency is he likely to designate to do his risk assessment work? Is it likely to be OMB or is it likely to be some other agency, and give us as much historical information as you can.

Mr. RITTER. I think OMB is going to be involved in these questions whether we have our bill or not. They are going to do the cost benefit approach. OMB is a budget organization; it is a budget operation.

My bill is not intended in any way to get into the judgments that are based on costs and benefits. My bill is simply to deal with the risks. Therefore, the agency that should conceivably oversee this kind of an approach, I would suspect, if I had my druthers, I would probably choose EPA, maybe have a several partite kind of a steering group as well. However, I think OMB is not the place because it will inevitably deal with the cost and the benefits and I don't think that is what this bill is about.

Mr. SCHEUER. Would you say that since the OMB is basically a budget decisionmaking entity, and since their processes are not public to my knowledge—certainly their decisionmaking processes on acid rain have not been public—as opposed to all of these other entities, and I will list them in the record, that have reported doing something on acid rain, starting with the National Academy of Sciences and the Senate Environment Committee.

[The list mentioned above follows:]

LIST OF GROUPS AND NATIONWIDE ORGANIZATIONS THAT HAVE CALLED FOR ACTION TO CONTROL ACID RAIN

The National Governors Association.
The National League of Cities.
The National Association of Counties.
The American Public Power Association.
The American Forestry Association.

The AFL-CIO Industrial Union Department.
The Atlantic Salmon Foundation.
The Amalgamated Clothing and Textile Workers.
The American Lung Association.
Citizens for a Better Environment.
The Coalition of American Electricity Consumers.
The General Motors Corporation.
The Garden Clubs of America.
The Environmental Defense Fund.
The Environmental Policy Center.
The Environmentalists for Full Employment.
The Friends of the Earth.
The International Association of Machinists and Aerospace Workers.
The Izaak Walton League of America.
The League of American Wheelmen.
The League of Women Voters of the United States.
The National Association of Railway Passengers.
The National Audubon Society.
The National Consumers League.
The National Farmers Union.
The National Parks and Conservation Association.
The National Urban League.
The National Wildlife Federation.
The Natural Resources Defense Council.
The Oil, Chemical and Atomic Workers International Union.
The Sierra Club.
The Soil Conservation Society.
The Union of American Hebrew Congregations.
The United Methodist Church—Board of Church and Society.
The United Steel Workers of America.
Trout Unlimited.
The Wilderness Society.
The Western Organization of Resource Councils.

Mr. RITTER. They are a Republican committee and they accepted it, and the House Democratic committee rejected it, so you can't really blame it on OMB.

Mr. SCHEUER. Nobody is blaming anything. I am simply pointing out that the process by which these several dozen groups, and I will ask unanimous consent to list them in the record, by which they came to their conclusions were public, and OMB was private. It seems to me that that may well be an element in your feeling that it ought to be EPA rather than OMB that will be the President's designated agency.

Mr. RITTER. Yes.

Mr. SCHEUER. Under your bill. I think it is important, and I think you think it is important to have it a public process.

Mr. RITTER. Yes, I do, to have an open public process. And, as much, this bill is intended for public consumption, the respective knowledge of various risks and hazards and concerns, so that they can make better decisions, so that their elected officials can make better decisions. We have seen regulatory decisions in some of these areas being made and something gets leaked somewhere. It gets leaked to an element in the media. Before you know it, there are certain activist elements that are involved, the media is involved, sensation is involved, and the scientific component is so distant from the decision process at that point that we all lose.

What is happening in the lack of literacy in this kind of area, lack of open involvement between the Federal agencies and the public with some knowledge of hazards and perspective and comparative risks, we are regulating out of fear. We are regulating out of sensation. We need a modicum more of science. We are not putting this in series circuit.

Dr. Ashford's fears I think have some merit if this process was a kind of series circuit or direct in line process with a regulatory decision forced and closed. But, what we are talking about is exposure. What we are talking about is building understanding. What we are talking about is bridges between these rather complicated subjects and the public and the media and having a role for the Federal agencies, not just for his Center for Policy Alternatives. Somehow, we are too limited at the present time.

Dr. **Ashford**. Don, first, I wish you wouldn't keep referring to the Center for Policy Alternatives as a major actor in this. We are a very small operation and we are not doing all the risk assessment that the Nation needs. I am not here to promote those wares.

However, since you yourself admitted that your preference might be to choose EPA as the coordinating agency, I would like to ask a question. I would like you to educate me. Why does your bill transfer to the President the authority to designate the agency? From an administrative, governmental analysis perspective, from my training as an attorney, some student of constitutional history of the Republic, I don't understand why you want the President to make this choice. Why doesn't your committee make the choice?

Mr. **Ritter**. I think that is a very good question. As you know, there have been shifts and changes in the EPA that are perhaps completed at the present time. It was done to provide an element of flexibility. As the process evolves, we are seeing different quarters play different roles and some better than others and some more than others. We are trying to keep this from being a turf battle between agencies. We are trying to keep one agency from trying to outlobby the other to have command and control. That is the reason.

Dr. **Ashford**. You see, I think you might be able to persuade me to support your general desire as you have articulated it if you could find a mechanism to take it out of the political realm, and particularly, designate a lead agency that I felt would be as free from political manipulation as is reasonable to expect. If my support means anything to you, and I am not saying that it should, but if my support for this exercise means anything to you, since we are in fundamental agreement that risk assessment is an important science to advance, then I would ask you to consider changing the objections that I have.

Mr. **Ritter**. What would you suggest?

Dr. **Ashford**. I have already made a suggestion, for example, that the National Institute for Environmental Health Sciences, either by itself or in coordination with NIOSH, which are nonregulatory agencies who are dedicated to science and investigation, might be the lead agency to oversee what in fact has been done. That is going a long way to removing, in my view, the possibilities for this political manipulation.

Mr. **Ritter**. I think it is something to discuss. The problems that I have there and the reason we went otherwise, I would prefer that what we do has some measure of importance and has some measure of meaning. It is not just another study group. The problem is that if you take it out of the center of activity, it ends up in the periphery. At that point, why don't we just stick with the National Academy of Sciences?

Dr. **Ashford**. Because NIEHS is a scientific organization which is not at the periphery. It is the place where the regulatory agencies very often get their information, so we are not talking about the periphery. We are talking about the center of respected scientific research, the NIH Institutes.

You and I disagree about whether we are overregulating or underregulating or the agencies have been good or bad. We don't need to agree on those things. That is not important. We do agree that risk assessment is important.

Mr. **Ritter**. My feeling there, now, is that the importance of risk assessment will be greater and will enter further into the regulatory process if it is not relegated to the outside of the decision mainstream.

Dr. **Ashford**. But NIH is outside the mainstream. I believe, unlike you, that you are going to set the stage with this bill for a high politicization of the scientific process. We just disagree.

Mr. **Ritter**. We have very different views, obviously, on the success and the lack of success of our regulatory process. Dr. Huber has had some very interesting work done on regulation that may have assisted in cleanup and in environmental control that had a chance of perhaps being more effective than the kind of regulation that we have seen. We are spending about $60 billion annually on health, safety, and environmental regulations.

Now, I am quoting a recent article in Fortune magazine by Stuart Eisenstadt; there may be other views. Are we getting the most for our money? I think we have to ask, are we getting the most for our money, or have we set certain stages because of a lack of science, good science, in those public policy decisions that have given us regulatory overburden which is awfully expensive and is not doing the job as it might.

Dr. **Ashford**. We might not be doing a good job, but your conclusion that it is the science that has been faulty, I think, is where we disagree.

Mr. **Ritter**. It is the entry of science into the public policy debate. What I want to see is a better entry, a higher level entry, a more mainstream entry. The National Academy can go off and do its assessments for umpteen years, but unless we in the Congress and the Government decide to really mainstream some of the things that they are coming up with, we are not going to change the system, and I think the system can be made better. It can be made more expeditious. The environment can be made cleaner.

Dr. **Ashford**. But the technical advisory committee functions which were, in fact, disembowled by the Reagan administration, were working very well. The EPA Science Advisory Board injected from a variety of political points of view technical information which was utilized until it was stopped.

Mr. **Ritter**. I disagree. I have a very intimate knowledge of some of the EPA advisory boards which weren't called upon, which when they were called upon, weren't used, which during the Carter administration tried to put some kind of perspective on hazards and were ignored. I guess my idea is that we are seeking a greater mainstream of some good science and we don't want to relegate it to just the R&D people. We want the R&D to be in the center of the action.

Do you have a comment on that, Dr. Rodricks or Dr. Huber?

Dr. **RODRICKS**. I would like to make one comment about the possible abuse of science or scientific information in the process. It is something that our committee at NRC considered at great length and was really the basis for a recommendation that we ensure a distinct separation between assessment and management, a clear separation between the two activities. The problem arises when one considers that the assessment process itself is not a process which is or can be, at this stage of our knowledge, completely objective.

To complete a risk assessment, one needs to inject a variety of assumptions. They are scientifically based, to be sure, but they can lead to quite different results. Values can certainly play a role in the selection of those assumptions to complete a risk assessment.

One of the recommendations of our committee was to want to make sure that we understood that those kinds of value judgments were distinct from and different from the value judgments we need to make for risk management decisions, and then do something to, if you like, encode the value judgments that the Federal agencies make when they carry out a risk assessment to protect them in some way, but at the same time, as I think your bill would do, to raise them to some scrutiny so that we understand both the value and scientific components of risk assessment. As I read the bill, I think that is a major component of the bill, and I think that is something quite in line with what the academy report has recommended.

Mr. **RITTER**. Let me ask you this. In my discussions with many members of the academy team, they have been very supportive of our legislation. I know they generally don't take positions on this sort of thing, I don't believe. What basically is the feeling of the National Academy toward this legislation? I had assumed it was fairly positive.

Dr. **RODRICKS**. I don't know the answer to that, Congressman. I was a member of the committee. I have stayed in touch with members of the committee and the academy. I don't know if the academy has a position.

Mr. **RITTER**. I don't know. I know the academy generally does not take positions on legislative initiatives. However, my understanding in speaking with members of the committee who dealt with the major study was that they were very much in favor of the kind of things that I was promoting.

Dr. **RODRICKS**. I think that is correct. I can't speak for every member of the committee, but those I have spoken with support title I. There were strong reservations about some components of title II, and I think that is where most of the discussion focused. However, I think with regard to title I, assuming we have some clarification of what risk assessment is and what you mean it to encompass—I still think there is some ambiguity there, and I hope you will consider further——

Mr. **RITTER**. I will certainly consider the kind of language that you recommend.

Mr. **SCHEUER**. Just as a matter of convenience, we can and will ask the NAS if they care to comment on the bill, and we can canvass the individual members of their committee to comment on the bill, and we will pass whatever we get on to you immediately, Congressman.

Mr. RITTER. Thank you. I have no further questions, Mr. Chairman.

Mr. SCHEUER. It has been a very interesting panel and I thank you all for your patience.

We will now go to the last two individuals who will testify. First, we will ask Michael Jacobson to come forward. He is executive director for Science in the Public Interest.

STATEMENT OF DR. MICHAEL JACOBSON, EXECUTIVE DIRECTOR, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, ACCOMPANIED BY BRUCE SILVERGLADE, LEGAL DIRECTOR

Dr. JACOBSON. Good morning, Mr. Chairman, Congressman Ritter.

Mr. SCHEUER. Would you take the same 7 or 8 minutes to sum up your views, and then I am sure we will have some questions for you, and while you are speaking, you are more than welcome to refer to any of the dialog that you have heard this morning.

Mr. JACOBSON. OK. Thank you.

My name is Michael Jacobson. I am executive director for the Center for Science in the Public Interest located here in Washington. I hold a bachelor's degree in chemistry from the University of Chicago and a Ph.D. in molecular biology from MIT. With me today is Bruce Silverglade, CSPI's legal director. The Center for Science in the Public Interest is a nonprofit consumer organization that specializes in health and environmental issues.

We have participated over the years in discussions about risk assessment, especially in connection with our work on nutrition and food safety. Risk assessment can potentially become a useful technique to help Government regulators quantify the severity of adverse effects from toxic substances and then propose suitable control measures.

As a scientist, I am almost instinctively attracted to risk assessment. At this time, however, risk assessment is still in its infancy. The technique is certainly more of an art than a science. Accordingly, we believe that the demonstration projects called for in H.R. 4192 are premature. Efforts in this area would be better directed toward basic research aimed at resolving a number of scientific problems that now make risk assessments unacceptable as the basis for making regulatory decisions.

Reliance on risk assessment for regulatory decisions raises two broad concerns. First, methodologies for extrapolating risk data are unreliable. For example, analyses of cancer risks utilize various theoretical mathematical models to extrapolate the estimated risk to the general human population from the results of small animal studies. However, while animal studies can be very useful in identifying human carcinogens, uncertainty about how the carcinogenic mechanism operates and basic differences between laboratory animals and humans make it nearly impossible to use animal data to determine accurately the magnitude of a cancer risk to humans. Moreover, the scientific community has not reached any consensus on which mathematical model is most appropriate in any given situation. Nevertheless, the choice of a particular model is crucial, because it often influences greatly the outcome of the analysis.

In the National Academy of Sciences report on saccharin, an estimate of risk posed by saccharin to the human population was calculated using four different mathematical models. The results from the different models varied over a range of 5 million. Thus, if the model used is the wrong one on which to base the risk assessment, the error can be large and possibly engender serious public health consequences or, alternatively, greatly overestimate a risk. Not surprisingly, the NAS panel on saccharin, as well as the industry supported Food Safety Council, have concluded that extrapolating from experimental animals to humans could not be made with confidence at present.

The difficulty of determining the degree of cancer risk to humans from the results of animal tests can be traced to several factors in addition to several differences between the species. For instance, experimental animals are carefully exposed to only a single suspected carcinogen. Interactions with any other cancer-promoting or cancer inhibiting substances in the animal's environment are not accounted for. Therefore, animal tests do not resemble the human experience where individuals are exposed to a wide variety of carcinogens and other chemicals in the course of leading normal lives.

Another reason is that laboratory animals are kept in peak physical condition. They are fed excellent diets, are protected from germs, do not take prescription drugs, do not smoke cigarettes, and do not drink alcohol. In humans, however, any of these factors may affect the cancer-causing potential of the chemical being tested.

Another reason is that scientists use highly inbred test animals. These test animals may be far more resistant or far more susceptible to cancer than many human beings who reflect diverse genetic backgrounds, again, thus either underestimating or overestimating the risk imposed by a certain chemical.

These and other factors make it difficult to extrapolate accurately the human risk of cancer from the results of animal tests.

Cancer, of course, is not the only chronic health hazard that would be subjected to risk assessment, although it is one that is often talked about. Examples from several other fields indicate some of the general concerns we have expressed about the premature use of risk assessment in governmental decisionmaking.

One example is cobalt. It is a mineral that is part of vitamin B-12, a mineral that everyone knew was safe. A risk analysis would have said zero risk. When cobalt was used as an additive in beer 20 years ago, the harmless chemical killed dozens of drinkers. The catch? Cobalt can be deadly to heavy drinkers whose hearts have been weakened by chronic drinking. Cobalt, and no other chemical that I know of, has been tested on animals and humans who consume large amounts of alcohol.

Sulfur dioxide is another example. It has been used for years, centuries, as a preservative in wine, salads, shrimp, and other foods. A risk analysis would have found little or no problem with this additive. In the last decade, researchers discovered that many people, especially people suffering from asthma, are acutely sensitive to sulfur dioxide and related additives. We have traced deaths of two middle-aged men to sulfur dioxide used in restaurant foods.

Interactions between chemicals abound, but they are never tested for or only very occasionally. While some chemicals by themselves cause birth defects, they cause many times more birth defects when administered together with caffeine, a substance consumed by a sizable percentage of pregnant women.

Going on to a second broad concern about jumping on to a risk-assessment bandwagon is that neither the scientific community nor Federal officials have come to grips with what is called in this bill risk evaluation, defining acceptable levels of risk. We note that H.R. 4192 also fails to define acceptable risk. Instead, the responsibility would fall on regulatory agencies such as FDA or perhaps it might reside at OSTP or some other agency, OMB if the President so designates.

FDA may decide, for example, that substances that cause less than one cancer in 1 million people over their lifetime pose an acceptable risk and should therefore be permitted in foods. FDA, in fact, is moving along this vein. Cancer patients might well argue that a 1 in 1 million risk of cancer from an artificial food flavoring is too big a risk. On the other hand, at least one influential industry attorney, a former general counsel of the Food and Drug Administration, has urged FDA to ban an additive only if it caused cancer in more than 1 percent of the population, or more than 2 million cancer deaths. That is this gentleman's cutoff.

Ultimately, with nothing in the statute, the definition of acceptable risk would not be known until the issue was extensively litigated. Yet, public debate is a vital aspect of health and safety regulation. Decisions of this type should not be made by judges or within the confines of an administrative agency. If Congress chooses to mandate risk assessment, then our elected Representatives themselves should discuss, in the public forum, and specify the degree of risk, how many people should die, specify this degree of risk to which the public will be subjected.

All this is not to say that risk assessments do not have a useful purpose. On the contrary, risk analyses or risk assessments have already played a useful role in certain regulatory matters. We understand that FDA officials frequently have done rough, informed risk analyses to sort out their priorities. We do that, also, at our organization. At present, risk analyses should continue to be used in this manner. Moreover, the development of methods to assess risks accurately and reliably are desirable, but today's risk assessments are not sufficiently reliable to be used as a basis for regulatory decisions.

Rather, funds should be appropriated for both basic research as well as analyses of the current state of the art that will help us understand dose-response relationships, interactions between chemicals, special sensitivities of different population subgroups, and other factors that are extremely important in developing accurate risk analyses before ordering regulators to base their decisions on risk analyses. This kind of work would most appropriately be supervised by an agency like the National Science Foundation, National Institutes of Health, or possibly a committee appointed by the NAS.

In addition to these general concerns, we would like to note several particular difficulties with the approach taken in H.R. 4192. First, section 109 specifically denies to agencies additional appropriations necessary to carry out the requirements of the bill. This point is crucial, because agencies are already suffering from budget cuts. It is likely that either the quality of demonstration projects produced under this legislation will suffer due to a lack of resources or funds diverted for these new projects will starve other projects.

Section 102(e) of the bill notes that risk evaluation is judgmental. Because evaluation is so judgmental, it is especially susceptible to political influence. Accordingly, it is necessary to ensure that the risk-evaluation process is isolated from politics.

Unfortunately, H.R. 4192 gives the President a free hand in choosing the agency that will coordinate risk evaluations. Congress itself, as the branch of government most representative of the public, should take the responsibility for specifying which agency should coordinate risk assessments and in defining some of the unknowns that would be used in risk assessments, such as levels of acceptable risk.

We are also concerned by the bill's reference to comparative risk assessment. Though the intent is obscure, we have noticed defenders of toxic chemicals scurrying around to find large risks, such as cigarette smoking, next to which their products appear relatively benign. The Congress should not support legislation that would be a vehicle for systematically diminishing the apparent magnitude of risks.

Finally, to follow up, I think, on the previous panel, Dr. Ashford in particular, I think that a bill on risk assessment would be a real contribution to the public debate pertaining to a whole range of health and environmental problems. I think a bill like H.R. 4192 could be greatly improved by four specific measures: first, designating NIEHS, as Dr. Ashford suggested, or some other scientific agency to coordinate the activities; second, appropriate funds for research instead of playing the old Washington game of piling on responsibilities without adding any funding; third, drop the demonstration projects; and fourth, let Congress specify what it believes are acceptable levels of risks.

Thank you very much, Mr. Chairman, for this opportunity to testify. We would be pleased to answer any questions that you or Mr. Ritter may have.

[The prepared statement of Dr. Jacobson follows:]

Testimony

Before the

Committee on Science and Technology
Subcommittee on Natural Resources,
Agriculture Research and Environment

HEARINGS

on H.R. 4192
The Risk Assessment Research and Development Act of 1983

U.S. House of Representatives

* * * * * * *

May 17, 1984

Michael F. Jacobson, Ph.D.
Executive Director

Center for Science in the Public Interest
1501 16th Street, N.W.
Washington, D.C. 20036

Good morning. My name is Michael Jacobson. I am Executive Director of the Center for Science in the Public Interest. With me today is Bruce Silverglade, CSPI Legal Director. The Center for Science in the Public Interest is a non-profit consumer organization that specializes in health and environmental issues. CSPI was founded in 1971 and is now supported by approximately 30,000 dues-paying members.

We have participated over the years in discussions about risk assessment, especially in connection with our work on nutrition and food safety. Risk assessment can potentially become a useful technique to help government regulators quantify the severity of adverse effects from toxic substances and then propose suitable control measures. At this time, however, risk assessment is still in its infancy. The technique is certainly more of an art than a science. Accordingly, we believe that the demonstration projects called for in H.R. 4192 are premature. Efforts in this area would be better directed towards basic research aimed at resolving a number of scientific problems that now make risk assessment unacceptable as a basis for making regulatory decisions. This view is shared by not only consumer representatives, but members of the Administration.

Assistant Secretary for Health Edward N. Brandt, Jr., recently stated

> Risk assessment is not an inappropriate approach to the problems of regulation. Rather, the real problem is that we simply do not yet have the appropriate scientific base to use risk assessment with full

> confidence in making many regulatory decisions.[1]

Reliance on risk assessment for regulatory decisions raises two broad concerns.

(1) First, methodologies for extrapolating risk data are unreliable. For example, analyses of cancer risks utilize various theoretical mathematical models to extrapolate the estimated risk to the general human population from the results of small animal studies. However, while animal studies can be very useful in identifying human carcinogens, uncertainty about how the carcinogenic mechanism operates makes it nearly impossible to use animal data to determine accurately the magnitude of a cancer risk to humans.[2] Moreover, the scientific community has not reached any consensus on which mathematical model is most appropriate in any given situation.[3]

---

[1] *Hearings on Review of Staff Report "Regulatory Procedures and Public Health Issues in the EPA's Office of Pesticide Programs," Before the Subcomm. on Department Operations, Research, and Foreign Agriculture of the House Comm. on Agriculture*, 98th Cong., 1st Sess. (1983)(statement of Edward N. Brandt, Jr., Assistant Secretary for Health, Dep't of Health and Human Services).

[2] The National Academy of Sciences (NAS) has concluded that "uncertainty about carcinogenic mechanisms makes it impossible to use animal data to estimate with confidence the degree of human risk." COMMITTEE FOR A STUDY ON SACCHARIN AND FOOD SAFETY POLICY, INSTITUTE OF MEDICINE AND THE NATIONAL RESEARCH COUNCIL/ASSEMBLY OF LIFE SCIENCES, FOOD SAFETY POLICY: SCIENTIFIC AND SOCIETAL CONSIDERATIONS, Part 2, 5-23 (1979).

[3] *See* FOOD SAFETY COUNCIL, A PROPOSED FOOD SAFETY EVALUATION PROCESS, FINAL REPORT OF BOARD OF TRUSTEES 58-59 (1982).

Nevertheless, the choice of a particular model is crucial, because it often influences greatly the result of the analysis.

In the National Academy of Sciences' (NAS) 1979 report on saccharin and food safety policy,[4] an estimate of risk posed by saccharin to the human population was calculated using four different mathematical models. The results from the different methods varied five million-fold, from an estimated 0.007 to 3640 cases of bladder cancer per 50 million people exposed to saccharin.[5] Thus, if the model used is the wrong one on which to base the risk assessment, the error can be large and possibly engender serious public health consequences or, alternatively, greatly overestimate a risk. Not surprisingly, the NAS Panel on Saccharin concluded

> [B]ecause of the substantial uncertainties in extrapolating from experimental animal doses to human exposure levels, the ... quantitation of risks to humans could not be made with confidence at present.[6]

Similarly, the Food Safety Council, an organization sponsored by the food industry, concluded after reviewing all of the mathematical models that

> Quantitative risk assessment is still subject to argument and further development. A number of mathematical models have been proposed to estimate dose response below the level used in experiments....

---

[4] INSTITUTE OF MEDICINE, _supra_ note 8.

[5] _Id._, Part 1 at 3-72

[6] _Id._, Part 2 at 3-6.

accurately the human risk of cancer from the results of animal tests. Cancer, of course, is not the only chronic health hazard that would be subjected to risk assessment. And examples from several fields indicate some of the general concerns we have expressed about the premature use of risk assessment in governmental decision-making.

* Cobalt is a mineral that is part of vitamin B-12 and that everyone knew was safe. A risk analysis would have said "zero risk." When cobalt was used as an additive in beer twenty years ago, the harmless chemical killed dozens of drinkers. The catch? Cobalt had never been tested on animals or humans who consumed large amounts of alcohol. Cobalt can be deadly to heavy drinkers whose hearts have been weakened by chronic drinking. There are about ten million alcoholics in the U.S.

* Sulfur dioxide has been used for many years as a preservative in wine, salads, shrimp, and other foods. It has always been considered relatively safe. A risk analysis would have suggested little or no problem with this additive. In the last decade, researchers discovered that many people, especially people suffering from asthma, are acutely sensitive to sulfur dioxide and related additives. We have traced two deaths of two middle-aged males to sulfur dioxide in restaurant foods.

* Japanese researchers find that cigarettes cause little increase in heart disease in their population. However, when cigarettes are smoked by people who eat a high fat diet, they are a potent promoter of coronary heart disease.

* Interactions between chemicals abound. Researchers at Children's Hospital in Cincinnati found that while some chemicals by themselves cause birth defects, they cause many times more birth defects when administered together with caffeine, a substance consumed by a high percentage of pregnant women.

(2) Second, reliance on risk assessment for regulatory decisions may prove difficult, because neither the scientific

community nor federal officials have come to grips with what is called "risk evaluation," i.e., defining acceptable levels of risk. We note that H.R. 4192 fails to define acceptable risk. Instead, the responsibility would fall on regulatory agencies such as the FDA. FDA has in fact already begun this task in formulating its constituent policy by requesting comments on what an acceptable risk level is.[8] FDA may decide, for example, that substances that caused less than one cancer in a million people over their lifetime pose an acceptable risk and should therefore be permitted in foods. However, even if only half of the 2500 food additives to which we are exposed carried this small risk, then the total cancer rate in humans would rise about 1 percent, from 25 to 26 percent (which is about 4000 additional deaths a year). Cancer patients might well argue that a one in a million risk of cancer from an artificial food flavoring is too big a risk. On the other hand, at least one influential industry attorney has urged FDA to ban an additive only if it caused cancer in more than 1 percent of the population--or more than two million cancer deaths.[9]

---

[8] Under the constituent policy, the FDA has proposed that food additives that contain a carcinogenic constituent need not be banned under the Delaney Clause. See 47 Fed. Reg. 14,464 (1982).

[9] Hutt, Unresolved Issues in the Conflict Between Individual Freedom and Government Control of Food Safety, 33-34 (paper presented at Conference on Public Control of Environmental Health Hazards, N.Y. Academy of Sciences, New York, June 29, 1978).

For this reason, determining an acceptable risk figure has been difficult and fraught with controversy. The Social and Economic Committee of the Food Safety Council was charged with this task, but its recommendations were rejected by the Council's Board of Trustees[10] and a consensus simply could not be reached. Given such difficulties, it is not surprising that H.R. 4192 fails to define an acceptable risk standard.

Ultimately, the definition of acceptable risk would not be known until the issue was extensively litigated. Accordingly, the precise definition of acceptable risk may ultimately be defined by judges in accordance with Justice Stewart's definition of pornography: "I know it when I see it."

Yet, public debate is a vital aspect of health and safety regulation. Decisions of this type should not be made by judges, or within the confines of an administrative agency. If Congress chooses to mandate risk assessment, then our elected representatives themselves should discuss and specify the degree of risk to which the public will be subjected.

Both facets of risk assessment, i.e., risk analysis and risk evaluation, are subject to political, social, and economic influences. Scientists are well aware of the policy implications of their findings, and it would be neither fair, not possible, for scientists to completely divorce scientific decisions from policy considerations. Thus, it is possible that political, social, and economic assumptions could influence the statements of even the most well meaning scientists about the risk from any particular chemical. Accordingly, risk assessments should not be relied upon as a completely objective, accurate technique, but rather viewed as a tool for making more explicit the policy judgments inherent in scientific decisions.

---

[10] FOOD SAFETY COUNCIL, supra note 9 at 19.

This is not to say that risk assessments do not have a useful purpose. On the contrary, risk assessments have already played a useful role in certain regulatory matters. For example, we understand that FDA officials have frequently done rough, informed risk analyses to sort out their priorities. We hope that the government will expand its use of approximate risk analyses to include not just potentially toxic chemicals, but also cigarettes, automobiles, and fatty meats. At present, risk assessments should continue to be used in this manner.

Moreover, the development of a mechanism to assess risks accurately and reliably is desirable. But today's risk assessments are not sufficiently accurate to be used as a basis for regulatory decisions. Rather, funds should be appropriated for both basic research and analyses of the state of the art that will help us understand dose-response relationships, pitfalls of animal testing, interactions between chemicals, special sensitivities of different population subgroups, and other factors that need to be resolved before regulators are ordered to base their decisions on risk assessment. This work would most appropriately be done by the National Science Foundation, National Institutes of Health, and a committee appointed by the National Research Council.

In addition to these general concerns, we would like to note several particular difficulties with the approach taken in H.R. 4192.

- Section 109 specifically denies to agencies additional appropriations necessary to carry out the requirements of the bill. This point is crucial, because agencies are already suffering from budget cuts. Based on past experiences, it is quite reasonable to predict that either the quality of any demonstration projects produced under this legislation will suffer due to a lack of resources or funds diverted for these new projects will drain other important activities of resources.

- As Section 102(e) of this bill notes, risk evaluation "is more judgmental in nature" than risk analysis. Because risk evaluation is so "judgmental", it is especially susceptible to political influence. Accordingly, it is necessary to ensure that the risk evaluation process is isolated from politics. Unfortunately, H.R. 4192 gives the President a free hand in choosing the agency that will coordinate risk evaluations, as well as risk analyses. Presumably, the President will choose OMB or OSTP to coordinate risk evaluations. Such a choice would be most unfortunate, because demonstration projects could be infused with political considerations. Congress itself should take the responsibility of defining some of the unknowns that would be used in risk assessment, such as levels of acceptable risk.

- We are concerned by the bill's (section 107(a)(8)) reference to comparative risk assessment. Though the intent is obscure, we have noticed defenders of toxic chemicals scurrying around to find large risks -- such as cigarette smoking -- next to which their products appear relatively benign. The Congress should not support legislation that would be a vehicle for systematically diminishing the apparent magnitude of risks.

This concludes our prepared remarks. We would like to thank the Subcommittee for this opportunity and would be pleased to answer any questions.

Mr. **Scheuer**. Thank you very much, Dr. Jacobson.

Congressman Ritter.

Mr. **Ritter**. I thank the chairman, and I thank the gentleman for his thoughtful testimony.

The first part was, as I take it, a generic overview of risk assessment, risk analysis and not in any way related to our bill.

Dr. **Jacobson**. Well, it is related in that I tried to suggest that there are severe limitations in making accurate risk analyses, as the NAS found when it tried to identify how much of a risk is posed to the human population by saccharin. When you start with animal studies, using a small number of highly inbred, short-lived animals, there are severe limitations. The NAS found that using different models of extrapolation based on a few limited studies, you can't come up with a very accurate figure.

Urging agencies to develop risk——

Mr. **Ritter**. Let me just deal with that one point. You talk about the NAS study on saccharin, but you don't weave that into what the Canadians have done and learned, coming up with some opposite results and some more sophisticated assessments, the aspartame, the cyclamate question. The fact that NAS, in 1983, has come out with a report that actively seeks the inclusion as a tool of assessments in these regulatory situations.

Let me make this point pretty clear, because in your testimony, you talked about using this as a basis for regulatory decisions. You talked about a congressional mandate to use this as a basis for regulatory decisions. The bill does not do this. The bill does not mandate risk assessment. The bill calls attention to risk assessment. It tries to coordinate capabilities in risk assessment. It does not mandate.

Dr. **Jacobson**. The bill mandates demonstration projects done at the various agencies.

Mr. **Ritter**. Yes; but the bill has absolutely nothing to do with a particular regulatory decision that will be published in a—that will be then a regulatory standard within a standard setting process. I would like to make that very clear.

I personally do not agree that risk assessments should be mandated across the board and in line with the regulatory decision process.

A couple of other points. You talked about ordering regulators to do this. We are not doing that. That is a major misconception.

Dr. **Jacobson**. Well, perhaps you could clarify it. As I understand it, the bill mandates risk assessments. The bill does not mandate exclusive use or application of those risk assessments with regard to——

Mr. **Ritter**. Sorry, the bill does not mandate anything. The bill mandates a demonstration project. The bill does not mandate risk assessments. The bill understands that risk assessment is going on. It seeks to better the techniques. It seeks to evolve the capability. It does not mandate risk assessment, and that is a very key point, because I personally do not feel that a mandated risk assessment, a kind of superimposition of risk assessment on anything and everything that has to do with health, safety, and environmental regulation is in order.

Dr. JACOBSON. As I read section 107(a), it says: "Each of the Federal agencies specifically designated in section 105(b)(2) shall undertake a risk assessment typical of that agency."

Mr. RITTER. Yes; if that sounds to you like a regulatory mandate to impose risk assessment on the standard setting process, then you have misinterpreted the bill.

Dr. JACOBSON. I think I understand the bill as saying the agencies shall undertake a risk assessment.

Mr. RITTER. A risk assessment as a demonstration and of the type that the agency normally does, and I happen to know that every one of these agencies already does it. So, that is very, very far from imposing a congressional mandate to do risk assessment within the line of the regulatory decision process.

Dr. JACOBSON. Well, you might want to change the language of the bill if many people have found that confusing.

Mr. RITTER. Well, you are the first one, but if you can find me others who are confused, I will clarify it.

Mr. SILVERGLADE. Congressman, wouldn't it be likely that the agency will do the risk assessment on a real life regulatory decision? It won't conduct it in the abstract. It is going to use this occasion, if it is required to do so by the bill, to conduct the risk assessment on a real, live regulatory decision.

Mr. RITTER. Yes, as a kind of example. However, when you talk about mandating risk assessment within the regulatory process which is what the first part of your testimony was criticizing, I agree. So, I don't think we disagree on that element.

Dr. JACOBSON. When you get numbers, a solid number, a number has a great momentum of its own, and——

Mr. RITTER. But you are talking about one risk assessment in a gargantuan Federal agency among tens of thousand of decisions that are being made on health, safety, and environmental questions. This is kind of an academic exercise, putting this risk assessment together.

But I want to get to something that I have heard before, and that is that somehow we don't provide the requisite funding for this. Frankly, I think that the Federal budgets in the regulatory agencies are big enough in their megabillion status to handle this kind of activity, considering that most of them, if not all, are already doing it.

The second aspect, and your criticism on section 102(e) that there is somehow a judgmental part of this situation, this bill does not mandate judgments in any way, shape, or form. I am not clear as to how your criticism of this bill being judgmental, where——

Dr. JACOBSON. The risk assessments, the risk evaluations are judgmental. You use judgments.

Mr. RITTER. But in that context, my God, everything we do here is judgmental. The risk assessments that have been underway for years and that have been incorporated in decision processes are all judgmental at some point. Everybody makes a judgment. The fact is that if you deny a judgmental perspective, you are not being realistic. There are always judgments being made. What we are trying to do is make better judgments. We are trying to infuse some scientific competence into the system to make better judgments.

Dr. Jacobson. I wouldn't object to that at all. I think the judgments should be made and are better made by scientific agencies like NCI or NIEHS rather than OMB or some agency that calls ketchup a vegetable.

Mr. Ritter. Well, having John Heinz as my State's Senator, I am not going to say anything against ketchup. I frankly do not agree that it is a vegetable.

You can isolate cute tales. What we are trying to do is evolve a process here, and in terms of risk evaluation and the process of risk evaluation, you mentioned that it must be isolated from politics. That is not true. Risk assessment should be isolated from politics, but risk evaluation is a political decision. It is a social, economic, political decision. To say somehow that risk evaluation should be isolated from politics is denying, in fact, the very criticisms that certain quarters have had for this bill that risk evaluation is a political decision and not a scientific decision wholly.

Your recommendations—I will consider your recommendations. But, again, I think on the NIEHS, we are talking about taking it out of the mainstream and relegating it to a quasi-academic body. We have done that already, basically. The Academy has done that.

More funds? There are billions of dollars out there, and they are already doing these things.

Drop the demonstration projects. Why? Why not expose to the public, and to the media, and to the various interest groups the nature and the rationale behind these kinds of decision processes?

Dr. Jacobson. If every agency has been using risk analyses in the past, I think the appropriate thing now would be to have an agency examine those, make a matrix, see how they have worked, what kind of problems did they run into, to what extent have they been used in regulatory matters?

Mr. Ritter. That is, to some extent, what we are doing, but we are seeking a kind of flexibility that doesn't all of a sudden put one agency in a super-control and involve all kinds of turf battles with 10 different other agencies. Every time you try to do some kind of interagency coordination, you run into problems. That is a problem that we recognize and we are trying to obtain the kind of flexibility that allows us to put the pieces together before everybody is battling over it.

I have one last comment. You talked about Congress, that it needs to specify acceptable levels of risk. Now, I don't know how you arrive at that decision, that it somehow should spell out beforehand acceptable levels of risk. I have dealt with TOSCA, RCRA, Superfund, nuclear power, coal, acid rain. There is no way that Congress, in its great wisdom, is going to provide a set of guidelines on acceptable levels of risk.

This is, indeed, the political side of the equation. This is risk evaluation. Each one is going to have a life and time all of its own, but the common ground could be that we have done a good job on the science. We have done a good job on the medical and the health effects side. We haven't run for a regulatory scheme that makes no sense at all and has nothing to do with public health but it is great politics and it is great sensation and it is great for the Center for Science in the Public Interest.

I am looking for a greater level of objectivity in what ends up as Congress setting acceptable levels of risk.

I have no more questions, and I thank the gentleman for his excellent testimony.

Mr. SCHEUER. Thank you very, very much, Dr. Jacobson.

I am going to ask unanimous consent that the record be left open in case Congressman Ritter or any other member of the panel has any further questions which can be answered in writing.

Thank you for your patience.

Now we will go to the last witness, Dr. Linda Randolph of the New York State Department of Public Health.

Dr. Randolph, we are running up against a time barrier here. You did submit a very technical paper that, frankly, is a little bit difficult, I think, for some of us to understand. If you would try to summarize, in layman's language, in 5 or 6 minutes, then we will have another 5, or 6, or 7 minutes to ask you some questions.

STATEMENT OF DR. LINDA RANDOLPH, NEW YORK STATE DEPARTMENT OF PUBLIC HEALTH

Dr. RANDOLPH. Thank you, Mr. Chairman. It is a pleasure for me to be here to discuss with you, Mr. Chairman, and the committee the important subject of risk assessment as a tool, and I would like to underline that word tool, because I have not heard that word used this morning in formulating——

Mr. RITTER. If the gentlelady will yield, was she here for my testimony?

Dr. RANDOLPH. I heard the first part.

Mr. RITTER. Did you hear my testimony prior to the other witnesses?

Dr. RANDOLPH. Yes.

Mr. RITTER. I talked about regulatory tool and regulatory toolbox, and that this is a regulatory tool——

Dr. RANDOLPH. No, I did not hear the toolbox; sorry.

Mr. RITTER. Oh, yes. I really used this.

Dr. RANDOLPH. All right. I stand corrected.

Although attempts to quantify health risks associated with radiation exposure and pesticide residues in foods have been made for several decades, only in the past decade with a greatly heightened public concern about exposure to toxic substances in the environment has risk assessment come to play a prominent role in the regulatory process. The problems are generally very complex. Nonetheless, conveying to the public the corresponding complexity of the risk assessment procedure is often difficult.

Although this procedure employs many toxicological principles and assumptions that are generally accepted in the field, no formula or set process for performing risk analysis exists for a particular situation. Any risk assessment makes assumptions concerning exposure and the extrapolation of toxicological data for humans or, more often, from animal data, to the problem under study. An essential step in the risk assessment process is to make all assumptions perfectly explicit so that their plausability can be judged by the policymakers and by others in the scientific community.

This morning, I will discuss very briefly the guidance for setting tolerance levels for EDB comparing risk assessments that were prepared by the New York State Department of Health, the U.S. Environmental Protection Agency, and by a consultant to the Grocery Manufacturers of America, Inc., or GMA, and I have submitted a copy of our detailed risk assessment.

The EPA risk assessment is contained in their documents 2, 3, and 4, and then the scientific support and decision document, dated February 8, 1984. The GMA consultant risk assessment we reviewed is dated January 20, 1984. I do understand that additional assessment of reproductive effects has been done but we have not had an opportunity to review it.

I will try to divide the presentation of the risk assessment procedure into five steps: formulating the problem and identifying the situation to be——

Mr. SCHEUER. Excuse me, is it the witness' intention to address Congressman Ritter's bill? This is what we are here this morning to consider.

Dr. RANDOLPH. My understanding was that we were to present a case study of the three risk assessments that were utilized in the establishment of certain regulatory policies as related to EDB. I think, from that, the issues that we were going to discuss would address those specific areas.

What I could do is perhaps define some of the issues relative to the assumptions that were made, the fact that those assumptions in our assessments were different, and the implications for assumptions as it relates to the bill. In essence, what we are saying is that risk assessment is important. Risk assessment is a tool. Risk assessment is based on a body of assumptions.

What has happened, perhaps unfortunately, is that those assumptions have not, first, been made explicit, and second, they have not been made public in order to be considered in an analysis of the ultimate policy decision that was ultimately made. We would stress very strongly that that process take place.

When we looked at the three risk assessments—I could summarize the major differences. One was that some risk assessments examine the risk from only single exposure while others looked at risk assessment from the standpoint of all exposure. Second, in terms of exposures, the risk assessments used different average daily intakes. Third, the risk assessments considered different effects. Some of the risk assessments only considered carcinogenic effects, and some risk assessments also took into consideration reproductive effects. In other words, some risk assessments took into account short-term effects as well as long-term effects.

There were assumptions that were made on the basis of the extent to which this particular pesticide was going to be in the marketplace as to whether or not a particular level would, in fact, be identified. On the basis of that, we came out with essentially three different levels at which policy decisionmaking was to be determined in terms of what was to happen.

I think that, in general, our position on the bill would be that anything that would strengthen the opportunity to enhance the capacity to use risk assessment is to be lauded and to be applauded.

We do have the concern which we raised with EPA when we first met with them, not only with New York State, but with the other State health officers, that in even the development of the assumptions and the risk analysis, most of their communication was with USDA and FDA. There had been no discussion with the State health department. There had been no discussion with public health.

If one looks at risk assessment and looks at what the public is asking for, the public's question is, what is the impact of risk on my health? In our particular State, when that question gets asked, the Department of Environmental Conservation asks the Department of Health to answer the question. However, we had not been involved to any measure in the development of the risk assessment. We feel that the public health—the scientific community that is involved in the policy development that relates to the health of the public and has an expertise for risk assessment should, in fact, be involved in this process and we would agree with some of the previous comments that have been made, perhaps not necessarily in terms of exactly or solely where the overall authority for this legislation should lie, but with a recommendation that an inclusion be made in terms of public health as one of those agencies. While not regulatorily responsible, we have a mission to address this issue and have the capacity to do so, and it is not mentioned in the legislation.

Mr. SCHEUER. Do you have any other remarks that you wish to address to the legislation, either supporting it or making any comment on it?

Dr. RANDOLPH. Just one other comment. There has been a lot of discussion about comparable risk assessments. One caveat that I would make about that is that it is important to not use that as a guise for not doing something. In other words, we should not say that until we have done all of the comparable risk assessments necessary to determine for any substituted entity, we cannot, therefore, take action on this substance at this time, given the information that we have available.

Mr. SCHEUER. Dr. Randolph, you have been very patient in waiting for several hours. We have enjoyed your testimony and benefited by it. It is a very sophisticated matter that you have treated in a very understanding way. Your full statement will be included in the record at this point.

[The prepared statement of Dr. Randolph follows:]

GOOD MORNING. I am LINDA RANDOLPH, DIRECTOR of the OFFICE OF PUBLIC HEALTH for the NEW YORK STATE HEALTH DEPARTMENT. It is a pleasure to be here this morning and to discuss with you the important subject of risk assessment as a tool in formulating public policy.

Although attempts to quantify health risks associated with radiation exposure and pesticide residues in food were made several decades ago, only in the past decade, with the greatly heightened public concern about exposure to toxic substances in the environment, has risk assessment come to play a prominent role in the regulatory process. The problems being addressed using risk assessment as a tool are generally very complex. Nonetheless, conveying to the public the corresponding complexity of the risk assessment procedure is often difficult. Although this procedure employs many toxicologic principles and assumptions that are generally accepted in the field, no formula or set process for performing a risk analysis exists for a particular situation. Any risk assessment makes assumptions concerning exposure and the extrapolation of toxicologic data, for humans or - more often - from animal data, to the problem under study. An essential step in the risk assessment process is to make all assumptions perfectly explicit so that their plausibility can be judged by the policy makers and by others in the scientific community.

This morning I am going to discuss three risk assessments that were prepared to provide guidance on setting tolerance levels for ethylene dibromide (EDB) in food. These risk assessments were prepared by the New York State Department of Health, the United States Environmental Protection Agency, and by a consultant to the Grocery Manufacturers of America, Incorporated (GMA). I am submitting a copy of our risk assessment with my presentation today. The USEPA risk assessment is contained in their Position Documents 2/3 and 4 and in the Scientific Support and Decision Document dated February 8, 1984. The GMA consultant risk assessment we have reviewed is dated January 20, 1984. I understand an additional assessment of reproductive effects has been done but we have not had the opportunity to review it. Comparing the different assumptions and procedures used at each step in the risk assessments should provide an interesting and valuable case study for the general process.

For today's presentation I have broken the risk assessment procedure into five steps: formulating the problem and identifying the situation to be assessed, estimating public exposure to the contaminant, selecting toxicological data to be applied, selecting a method to estimate human risks from the toxicologic data, and making a judgment regarding the level of acceptable risk or margin of safety. I will not attempt to provide an in-depth review of these risk assessments, but I do hope to convey a sense of the judgments that must be made at every step, judgments which inevitably lead to some differences in the estimated risks.

The basic formulation of the problem differs among the three risk assessments. The EPA risk assessment considers two to three year and lifetime exposure of population groups associated with the various uses of EDB. The New York State risk assessment considers the risks associated with lifetime exposure, the incremental risks associated with three years of exposure, and reproductive risks associated with short-term exposure. The GMA assessment considers only risks associated with exposure during a three year (or five year) phase-out, during which EDB use is halted and levels in food drop to zero.

The exposure estimates in the three risk assessments differ considerably. An exposure estimate consists of identifying the population groups at risk, defining routes of exposure for each of these population groups, and selecting quantitative exposure data characterizing these routes of exposure. The USEPA risk assessment focuses on three population groups, the general population, the child, and pesticide applicators. The routes of exposure considered for the general population are the diet and contaminated groundwater; estimated dietary exposure is from grains, citrus, and tropical fruits. Mean EDB levels for various regulatory options are estimated from residue monitoring data. It is assumed that enforcement removes from commerce 100% of all grain products containing residues above the proposed maximum residue level. EPA's estimates also assume an 80% loss of EDB in cooking intermediate products. EDB inhalation by the general population is not considered, whereas this exposure is the basis of the separate risk assessment for pesticide applicators. The quantitative data on inhalation exposure are derived from field monitoring of residual levels associated with agricultural uses which are then combined with data on dietary intake.

The New York State exposure estimates focus on three population groups, the general population, vegetarians, and young children. Exposure to all groups by ingestion and inhalation is considered. Dietary intake is estimated by assuming average concentrations in food as consumed, using available data on consumption of grains and citrus. Lacking dietary data for vegetarians, the assumptions are made that grain crops represent 50% and citrus products 10% of the diet of vegetarians, compared to 13.8% and 3.8%, respectively, for the general population. Inhalation exposure is calculated from measured EDB concentrations in the air of seven cities throughout the country. These EDB levels are associated primarily with the use of EDB as a scavenger in leaded gasoline.

The GMA exposure estimates identify the general population and young children as population groups at risk. Only dietary exposure is considered. The exposure data used are average concentrations in grain products found in market surveys conducted for the GMA. The further assumptions are made that EDB use has been discontinued, that future exposure will be due solely to passage of present products through the food distribution system, and that there will be a loss of 90% of the EDB in such products by evaporation before they reach the consumer.

A major difference among the three risk assessments is the values used for the average daily intake of grains and citrus for the general population and the child. The US EPA used an average daily intake of 133 grams of grain for adults; NYS used a level of 270 grams. The US EPA used an average daily intake of 53 grams of grain for a 1 year old child; NYS used an average daily intake of 103 grams of grain for a 2 year old child. GMA also supplied average consumption data to NYS which were in good agreement with that used by NYS.

All of these risk assessments use the 1978 National Cancer Institute carcinogenesis bioassay in which rats and mice were exposed to EDB via gavage. The New York State Health Department analyzed the data for the different tumors produced in different animal groups and found them to be consistent with the results from an inhalation study performed by the National Cancer Institute in 1982. The specific dose-response data used to estimate human cancer risks were those for stomach tumors in female mice, because they represent the most sensitive response found among the exposed animal groups. The US EPA and the GMA consultant used the results for stomach tumors in male rats from this same bioassay. In the New York State estimates of the incremental cancer risks from three years of exposure, a risk extrapolation model proposed by EPA in its position document #4 (the one-hit model with WEIBULL timing) was used. The parameters in this model appear to be based on the male rat data, but the documentation does not permit a clear conclusion on this point. I might comment that this is an important part of risk assessment that frequently does not receive proper attention. That is, it is essential to identify not only the experiment upon which assessments are based, but the specific group of animals used to provide the dose response data which are extrapolated in estimating human risks.

The New York State Department of Health considered reproductive risks associated with EDB, using data on effects in the male reproductive system of bulls and the results obtained by Adams, et al. (1984) and Smith and Goldman (1983) on behavioral effects in the progeny of rats exposed to EDB. The earlier EPA risk assessments also consider reproductive effects but did not employ the recent studies.

The method used by both the New York State Health Department and the EPA to estimate reproductive risks is the margin of safety approach, whereby the acceptable human daily intake is considered to be some fraction of that level at which no effect was produced in animal bioassay. Mathematical models are used to extrapolate cancer risks from animal data to humans in all three risk assessments. New York State used a multistage model which seeks the best fit of a general mathematical expression to the animal dose-response data. For the EDB cancer bioassay data used, however, toxic effects at the highest dose level made it necessary to eliminate this data point in deriving the extrapolation model, and the model is therefore reduced to the simpler one-hit extrapolation model. This same model is employed in the EPA and GMA consultant assessments. New York State also employs a 95% confidence limit on the resulting dose-response curve to estimate risks. It is not clear from the EPA report whether they use this confidence limit. New York State makes the additional assumption that the carcinogenic potency of EDB to humans and the test animals is the same when expressed in terms of dose per unit body surface area per day. Both the EPA and the GMA consultant use this procedure as well.

The New York State Department of Health based its regulatory decisions on maintaining a margin of safety for reproductive risks of at least 1,000 for the most sensitive group and on the need to keep excess cancer risks at a minimum. The industry consultant estimated the upper bound on the incremental lifetime cancer risks to be about one in two million, which is termed an "insignificant risk." The EPA evaluated the exposure, risk and economic consequences of implementing alternative maximum permissible residue levels and selected one of the options.

In summary, the major differences in the EDB risk assessments are (1) examining the risk from single exposure routes or examining the combined risk from all exposures; (2) using different average daily intake levels for grain and citrus products; and (3) using additional data on reproductive effects which were not available until late 1983 or early 1984. I thank you for this opportunity to discuss these issues with you.

Mr. **Scheuer**. Dr. Randolph, thank you very, very much for your testimony.

The subcommittee will stand adjourned.

[Whereupon, at 12:12 p.m., the subcommittee recessed, to reconvene at the call of the Chair.]

H.R. 4192, THE RISK ASSESSMENT RESEARCH AND DEMONSTRATION ACT OF 1983

TUESDAY, JUNE 5, 1984

HOUSE OF REPRESENTATIVES, COMMITTEE ON SCIENCE AND TECHNOLOGY, SUBCOMMITTEE ON NATURAL RESOURCES, AGRICULTURE RESEARCH AND ENVIRONMENT

Washington, DC.

The subcommittee met, pursuant to call, at 9:30 a.m., in room 2318, Rayburn House Office Building, Hon James H. Scheuer (chairman of the subcommittee) presiding.

Mr. **SCHEUER**. The Subcommittee on Natural Resources, Agriculture Research and Environment will come to order.

Today is the second day of hearings on title I of H.R. 4192, the Risk Analysis Research and Demonstration Act, introduced by Congressman Don Ritter of Pennsylvania.

On our first day of hearings, an impressive array of witnesses told us about the growing importance of risk assessment in the regulatory process. Most of the witnesses supported the general intent of H.R. 4192 to promote the use of better science in the risk assessments conducted by the Federal agencies.

At the same time, a number of witnesses cautioned that risk assessment was not an exact science, and that there remain significant gaps in our basic scientific knowledge that cannot be overcome simply by improving risk assessment procedures.

Other witnesses suggested that the role of promoting better risk assessments would be better assigned to an independent scientific organization rather than OMB or some other political entity.

Today we will hear from those serving in the front line of risk assessment, the four Federal agencies which are responsible for most of the major risk assessments. We are also fortunate to have with us other distinguished witnesses from a variety of backgrounds. We certainly look forward to their testimony.

Congressman Mike Andrews.

Mr. **ANDREWS**. I don't have an opening statement, Mr. Chairman.

Mr. **SCHEUER**. Congressman Tim Valentine.

Mr. **VALENTINE**. I don't have anything, Mr. Chairman.

Mr. **SCHEUER**. All right then, before we get to the three panels, we will hear from our colleague, Richard Ottinger of New York.

Congressman Ottinger, we are delighted to have you here today. Please proceed as you wish.

STATEMENT OF THE HON. RICHARD OTTINGER, A MEMBER OF CONGRESS FROM THE STATE OF NEW YORK

Mr. OTTINGER. I would like permission to submit a fuller statement for the record.

Mr. SCHEUER. Without objection.

Mr. OTTINGER. I congratulate you, Mr. Chairman, and members of the committee for holding these hearings on what is a very important subject indeed, and one of much controversy. Risk assessments in one sense is something that we all do everyday. "Should I or should I not cross that street against oncoming traffic?" or "What is the likelihood that if I don't study for the test tomorrow, that I will pass?" There are risks that we take everyday. We make judgments and decisions based on the information available to us, and we, as individuals, feel that we control our lives.

When risk assessment becomes a science, however, we cannot consider it in the same light as the judgments that we make everyday. In a nutshell, risk assessments are most useful when they illuminate, and most dangerous when they hide considerations that are relevant to decision. Unfortunately, this bill seems designed to hide rather than illuminate information relevant to decisions to which it addresses itself.

Mr. Ritter has introduced H.R. 4192 in an attempt to codify this new area of science. This bill would establish a Board of Scientific Risk Assessment to oversee the analysis done by various Federal agencies. It would be comprised of only individuals trained in the life sciences or physical sciences with no regard to social science, behavioral science, philosophy or ethics. This apparent lack of understanding of the importance of these disciplines is a serious shortcoming of this legislation.

Sometimes we have enough data to make reasonable conclusions about the safety of a technology. But more often than not, risk assessments depend heavily on guesswork—frequently called expert judgment, subject to policy rather than objective technical considerations.

These uncertainties are increased further when we are dealing with a relatively new technology and when the experts doing the risk assessment don't really have the expertise that is necessary. Many of today's most controversial technological issues—nuclear power, toxic waste disposal, genetic engineering—involve just the kind of questions that present data will not allow us to answer in technical definitive terms. Most of the risk assessments that have been done have not considered the effect of human actions on the technological risks despite the importance of so-called human error and other human factors in many technological areas.

The example of the different EDB analyses that New York State, EPA, and the grocery manufacturing industry did recently can be used to illustrate this point. Major differences in the studies derived from the fact that one study looked at a single exposure to EDB and the other studies looked at a combined exposure over a long period of time. They also differed in terms of how much contaminated grains and fruits they assumed people consumed.

In addition, EPA failed to look at the reproductive effects of EDB exposure but they did balance the economic consequences of discontinuing the use of EDB against the risks of exposure, something that the other analyses did not do. None of this is to say which of these assessments were more scientifically correct, but they certainly took different factors into account. Therefore, it is not unrealistic to assume that the conclusions that were drawn differed greatly.

It must be realized that the very complexity of analysis sometimes hides rather than highlights the judgment calls that the scientists make. In our democratic system, the people themselves and their elected representatives are the ones who are expected to exercise the final judgment on such questions. Thus the net result might be that we would be taking away from the public and their representatives the very kind of decisionmaking that they, rather than technical specialists, are best equipped to make.

This does not mean that I am advocating excluding technical specialists from our decision making. Rather I am advocating using them more appropriately than would be the case under the present version of this bill. They should be contributors to, not the final arbiters of life and death policy decisions.

One dollar may be interchangeable with another dollar, but how does one equate dollars and deaths, profits and pains, risks and rewards? Scientists cannot responsibly claim that one death equals a particular benefit. These complexities are hidden whenever a risk assessment comes to a bottom line body count, yet they are minor compared to the problems of equating deaths vs. disease, vs. dollars, weighing known benefits against expected costs, or uncertain risks against certain costs, comparing uncertain but irreversible costs against those that are relatively certain but reversible, or otherwise pitting apples versus oranges versus orangutans. Science provides no legitimate means for making these comparisons, nor will it ever in the future. Risk assessment requires value judgments that are beyond quantification. What is important is that such comparisons be made clearly and explicit, and be amenable to review rather than hidden by a technical smokescreen.

Even the most splendid assessment imaginable can leave major problems unexplained or incompletely understood—a problem that can be especially troubling because the risk assessment can leave the false impression that no stone has been left unturned, no possibility has been left out of consideration. This is related to one of the major problems in the technical community in the eyes of the general public; the "oops" phenomenon.

Scientist, like anyone else, often fail to consider all the relevant evidence and sometimes make mistakes. A sad example was a respected geologist who was on the top of Mt. St. Helens, making routine measurements when the top quarter mile of the mountain blew off. In retrospect, other geologists have been able to read the preeruption data as providing warnings of an imminent eruption, but this conclusion is obviously only in hindsight, and meanwhile an important scientist lost his life.

Another example is nuclear power which scientists assured the public would produce electricity too cheap to meter, and the Rasmusson report, a risk assessment, assured the public that the risk of a meltdown was one in a million. Three Mile Island and the current nuclear economic disasters show how little trust we can have in such bottom line statements.

The public remains concerned, and rightfully so, that data is often misused. And that this will lead to erroneous conclusions that certain technologies are safe. It is feared that the error of this misplaced confidence will become obvious only in retrospect.

In conclusion, Mr. Chairman, I would like to state again that I believe that this bill takes the wrong approach to risk assessment if what we want is for our society to reap the benefits of better risk assessment while avoiding some of the worst abuses. In order to provide a more positive contribution, a revised bill should:

First, emphasize the strengthening of very different areas of expertise that would do more to overcome the most important existing gaps in our knowledge—emphsizing research in the social and behavioral sciencies to improve our understanding of the human behaviors that have important implications for most kinds of technological risks, and work in ethics to provide better insight into the ethical implications of technologies that provide benefits and risks to different persons.

Second, work to develop new kinds of mechanisms. The bill, as currently written, would work to hide or even paper over the many kinds of problems for which scientific expertise provides no useful guidance. It needs to be rewritten to draw explicit attention to these problems and to develop new mechanisms for dealing with them: (*a*) Rather than trying to deny that real uncertainties exist, systematic analysis should attempt to provide policymakers and the general public with improved means for making good decisions even in the face of irreducible uncertainties, giving a fair hearing and improved understanding to the differing but often quite legitimate values underlying opposing points of view; (*b*) rather than always trying to develop "all other factors equal" predictions and assessments—assuming away surprises in an effort to develop point estimates of what are sometimes optimistically called most likely outcomes we may need systematic empirical research on the frequency with which such surprises occur, particularly as a result of human activities, and we may need to develop plans and procedures for dealing with the surprises rather than naively hoping that no such disruption will occur; and (*c*) we may need to develop new mechanisms to encourage scientists to provide technical input to the decision making process without attempting to disguise political judgments as supposedly scientific ones.

I thank you very much for the opportunity to testify and again congratulate you on exploring this very difficult and important topic.

[The prepared statement of Mr. Ottinger follows:]

CONGRESSMAN RICHARD L. OTTINGER
JUNE 5, 1984
TESTIMONY BEFORE
NATURAL RESOURCES, AGRICULTURE RESEARCH AND ENVIRONMENT SUBCOMMITTEE
OF THE
SCIENCE AND TECHNOLOGY COMMITTEE

RISK ASSESSMENT

H. R. 4192

MR. CHAIRMAN, I WANT TO THANK YOU FOR THE OPPORTUNITY TO PRESENT MY VIEWS ON THE SUBJECT OF RISK ASSESSMENT. RISK ASSESSMENT IN ONE SENSE IS SOMETHING THAT WE ALL DO EVERY DAY. "SHOULD I, OR SHOULD I NOT CROSS THAT STREET AGAINST ONCOMING TRAFFIC?" THERE ARE RISKS THAT WE TAKE EVERY DAY, WE MAKE JUDGEMENTS AND DECISIONS BASED ON THE INFORMATION AVAILABLE TO US. AND WE, AS INDIVIDUALS, FEEL THAT WE CONTROL OUR LIVES.

WHEN RISK ASSESSMENT BECOMES A SCIENCE ADDRESSING COMPLEX POLLUTION AND TECHNICAL QUESTIONS, HOWEVER, WE CANNOT CONSIDER IT IN THE SAME LIGHT AS THE JUDGEMENTS THAT WE MAKE EVERY DAY. IN A NUTSHELL, RISK ASSESSMENTS ARE MOST USEFUL WHEN THEY ILLUMINATE AND MOST DANGEROUS WHEN THEY HIDE CONSIDERATIONS THAT ARE RELEVANT TO DECISIONS. UNFORTUNATELY, THIS BILL SEEMS DESIGNED TO HIDE RATHER THEN ILLUMINATE INFORMATION RELEVANT TO DECISIONS.

MR. RITTER HAS INTRODUCED H. R. 4192 IN AN ATTEMPT TO CODIFY THIS NEW AREA OF SCIENCE. AMONG OTHER THINGS THIS BILL WOULD ESTABLISH A BOARD OF SCIENTIFIC RISK ASSESSMENT TO OVERSEE THE ANALYSIS DONE BY VARIOUS FEDERAL AGENCIES. IT WOULD BE COMPRISED OF ONLY INDIVIDUALS TRAINED IN THE LIFE SCIENCES OR PHYSICAL SCIENCES WITH NO REGARD TO SOCIAL SCIENCE, BEHAVIORIAL SCIENCE, PHILOSOPHY OR ETHICS. THIS APPARENT LACK OF UNDERSTANDING OF THE IMPORTANCE OF THESE DISCIPLINES IS A SERIOUS SHORTCOMING OF THIS LEGISLATION.

SOMETIMES WE HAVE ENOUGH DATA TO MAKE REASONABLE CONCLUSIONS ABOUT THE SAFETY OF A TECHNOLOGY. BUT MORE OFTEN THAN NOT, RISK ASSESSMENTS DEPEND HEAVILY ON GUESSWORK (FREQUENTLY CALLED 'EXPERT JUDGEMENT') AND SUBJECTIVE POLICY RATHER THAN OBJECTIVE TECHNICAL CONSIDERATIONS. THE APPARENT PRECISION OF NUMERICAL

RESULTS CAN BE MISLEADING AND IRRESPONSIBLE BECAUSE OF THE UNCERTAINTY INHERENT IN AN 'ESTIMATE'.

THESE UNCERTAINTIES ARE INCREASED FURTHER WHEN WE ARE DEALING WITH A RELATIVELY NEW TECHNOLOGY AND WHEN THE 'EXPERTS' DOING THE RISK ASSESSMENT DON'T REALLY HAVE THE EXPERTISE THAT'S NECESSARY. MANY OF TODAY'S MOST CONTROVERSIAL TECHNOLOGICAL ISSUES (NUCLEAR POWER, TOXIC WASTE DISPOSAL, GENETIC ENGINEERING) INVOLVE JUST THE KIND OF QUESTIONS THAT PRESENT DATA THAT WILL NOT ALLOW US TO ANSWER. MOST OF THE RISK ASSESSMENTS THAT HAVE BEEN DONE HAVE NOT CONSIDERED THE EFFECT OF HUMAN ACTIONS IN REGARD TO THE TECHNOLOGICAL RISKS DESPITE THE IMPORTANCE OF SO-CALLED 'HUMAN ERROR' AND OTHER HUMAN FACTORS IN MANY TECHNOLOGICAL AREAS.

SOME CONTROVERSIES CAN BE REDUCED TO "ANSWERABLE" TECHNICAL QUESTIONS; MANY CANNOT. THIS BILL WOULD APPEAR TO ENCOURAGE SCIENTISTS AND TECHNOLOGISTS TO COME UP WITH "ANSWERS" TO QUESTIONS THAT ARE INHERENTLY NONSCIENTIFIC - HOW SAFE IS SAFE ENOUGH? IS IT 'JUST' FOR A TECHNOLOGY TO HARM PERSON 'A' WHEN PERSON 'B' REAPS THE BENEFITS?

THE EXAMPLE OF THE DIFFERENT EDB ANALYSES THAT NEW YORK STATE, EPA, AND THE GROCERY MANUFACTURING INDUSTRY DID RECENTLY CAN BE USED TO ILLUSTRATE THIS POINT. MAJOR DIFFERENCES IN THE STUDIES DERIVED FROM THE FACT THAT ONE STUDY LOOKED AT A SINGLE EXPOSURE TO EDB AND THE OTHER STUDIES LOOKED AT A COMBINED EXPOSURE OVER A LONG PERIOD OF TIME. THEY ALSO DIFFERED IN TERMS OF HOW MUCH CONTAMINATED GRAINS AND FRUITS THEY ASSUMED THAT PEOPLE CONSUMED. IN ADDITION EPA FAILED TO LOOK AT THE REPRODUCTIVE EFFECTS OF EDB EXPOSURE BUT THEY DID 'BALANCE' THE ECONOMIC CONSEQUENCES OF DISCONTINUING THE USE OF EDB AGAINST THE RISKS OF EXPOSURE, SOMETHING THAT THE OTHER ANALYSES DID NOT DO. NONE OF THIS IS TO SAY WHICH OF THESE ASSESSMENTS WERE MORE SCIENTIFICALLY CORRECT, BUT THEY CERTAINLY TOOK DIFFERENT FACTORS INTO ACCOUNT. THEREFORE IT IS NOT UNREALISTIC TO ASSUME THAT THE CONCLUSIONS THAT WERE DRAWN DIFFERED GREATLY.

IT MUST BE REALIZED THAT THE VERY COMPLEXITY OF ANALYSIS SOMETIMES HIDES RATHER THAN HIGHLIGHTS THE JUDGEMENT CALLS THAT THE SCIENTISTS MAKE. IN OUR DEMOCRATIC SYSTEM, THE PEOPLE THEMSELVES AND THEIR ELECTED REPRESENTATIVES ARE THE ONES WHO ARE EXPECTED TO EXERCISE THE FINAL JUDGEMENT ON SUCH QUESTIONS. ADDITIONALLY IT IS INTERESTING TO NOTE THAT RESEARCH SHOWS TECHNICAL SPECIALISTS OFTEN DIFFER

SYSTEMATICALLY FROM THE GENERAL PUBLIC IN THEIR ANSWERS TO THESE NONSCIENTIFIC QUESTIONS. THUS THE NET RESULT MIGHT BE THAT WE WOULD BE TAKING AWAY FROM THE PUBLIC AND THEIR REPRESENTATIVES THE VERY KIND OF DECISION MAKING THAT THEY, RATHER THEN TECHNICAL SPECIALISTS, ARE BEST EQUIPPED TO MAKE. MOREOVER, TECHNICAL SPECIALISTS ARE AS PRONE TO OVERCONFIDENCE IN INCORRECT JUDGEMENTS AS ARE LAY PEOPLE, AND THE SPECIALISTS ALSO OFTEN FAIL TO POINT OUT WHEN THEY ARE SPEAKING FROM THEIR OWN PERSONAL VALUES RATHER THEN FROM A BASIS OF SCIENTIFIC FACT.

THIS DOES NOT MEAN THAT I AM ADVOCATING EXCLUDING TECHNICAL SPECIALISTS FROM OUR DECISION MAKING, RATHER I AM ADVOCATING USING THEM MORE APPROPRIATEY THAN WOULD BE THE CASE UNDER THE PRESENT VERSION OF THIS BILL. THEY SHOULD BE CONTRIBUTORS TO, NOT THE FINAL ARBITERS OF, LIFE AND DEATH POLICY DECISIONS.

WHAT DO WE DO WHEN THOSE WHO BENEFIT FROM A TECHNOLOGY ARE DIFFERENT FROM THOSE WHO PAY THE PRICE? SCIENCE CANNOT AND SHOULD NOT BE ALLOWED TO ANSWER THESE QUESTIONS. YET, SO-CALLED 'BOTTOM LINE' RISK ESTIMATES HAVE BEEN FAR FROM ADEQUATE IN INDICATING THE EQUITY OF COST-BENEFIT DISTRIBUTION, EVEN THOUGH MANY OF TODAY'S MOST COMPLEX TECHNOLOGIES ARE CONTROVERSIAL, IN PART, BECAUSE THE PEOPLE WHO SUFFER ARE DIFFERENT FROM THOSE WHO BENEFIT.

ONE DOLLAR MAY BE INTERCHANGEABLE WITH ANOTHER DOLLAR, BUT HOW DOES ONE 'EQUATE' DOLLARS AND DEATHS, PROFITS AND PAINS, RISKS AND REWARDS? SCIENTISTS CANNOT RESPONSIBLY CLAIM THAT ONE DEATH 'EQUALS' A PARTICULAR BENEFIT. THESE COMPLEXITIES ARE HIDDEN WHENEVER A RISK ASSESSMENT COMES TO A 'BOTTOM-LINE' BODY COUNT, YET THEY ARE MINOR COMPARED TO THE PROBLEMS OF EQUATING DEATHS VS. DISEASE VS. DOLLARS, WEIGHING KNOWN BENEFITS AGAINST EXPECTED COSTS, OR UNCERTAIN RISKS AGAINST CERTAIN COSTS, COMPARING UNCERTAIN BUT IRREVERSIBLE COSTS AGAINST THOSE THAT ARE RELATIVELY CERTAIN BUT REVERSIBLE, OR OTHERWISE PITTING APPLES VS. ORANGES VS. ORANGUTANS. SCIENCE PROVIDES NO LEGITIMATE MEANS FOR MAKING THESE COMPARISONS, NOR WILL IT EVER IN THE FUTURE. RISK ASSESSMENT REQUIRES VALUE JUDGEMENTS THAT ARE BEYOND QUANTIFICATION. WHAT IS IMPORTANT IS THAT SUCH COMPARISONS BE MADE CLEARLY AND EXPLICITLY, AND BE AMENABLE TO REVIEW RATHER THAN HIDDEN BY A TECHNICAL SMOKESCREEN.

AN "ACCIDENT", ALMOST BY DEFINITION, IS SOMETHING THAT WASN'T EXPECTED, AND EVEN THE MOST SPLENDID ASSESSMENT IMAGINABLE CAN LEAVE MAJOR PROBLEMS UNEXPLAINED OR INCOMPLETELY UNDERSTOOD - A PROBLEM THAT CAN BE ESPECIALLY TROUBLING BECAUSE THE RISK ASSESSMENT CAN LEAVE THE FALSE IMPRESSION THAT NO STONE HAS BEEN LEFT UNTURNED, NO POSSIBILITY HAS BEEN LEFT OUT OF CONSIDERATION. THIS IS RELATED TO ONE OF THE MAJOR PROBLEMS OF THE TECHNICAL COMMUNITY IN THE EYES OF THE GENERAL PUBLIC; THE "OOPS" PHENOMENON. SCIENTISTS, LIKE ANYONE ELSE, OFTEN FAIL TO CONSIDER ALL THE RELEVANT EVIDENCE AND SOMETIMES MAKE MISTAKES. A SAD EXAMPLE WAS A RESPECTED GEOLOGIST WHO WAS ON THE TOP OF MT. SAINT HELENS, MAKING ROUNTINE MEASUREMENTS, WHEN THE TOP QUARTER MILE OF THE MOUNTAIN BLEW OFF. IN RETROSPECT, OTHER GEOLOGISTS HAVE BEEN ABLE TO "READ" THE PRE-ERUPTION DATA AS PROVIDING WARNINGS OF AN IMMINENT ERUPTION, BUT THIS CONCLUSION IS OBVIOUS ONLY IN HINDSIGHT, AND MEANWHILE, AN IMPORTANT SCIENTIST LOST HIS LIFE.

ANOTHER EXAMPLE IS NUCLEAR POWER WHICH SCIENTISTS ASSURED THE PUBLIC WOULD PRODUCE ELECTRICITY 'TOO CHEAP TO METER' AND THE RASMUSSON REPORT, A RISK ASSESSMENT, ASSURED THE PUBLIC THAT THE RISK OF A MELTDOWN WAS ONE IN MILLIONS.THREE MILE ISLAND AND CURRENT NUCLEAR ECONOMIC DISASTERS SHOW JUST HOW LITTLE TRUST WE CAN HAVE IN 'BOTTOM LINE' STATEMENTS.

THE PUBLIC REMAINS CONCERNED, AND RIGHTFULLY SO, THAT DATA IS OFTEN MISUSED. AND THAT THIS WILL LEAD TO ERRONEOUS CONCLUSIONS THAT CERTAIN TECHNOLOGIES ARE 'SAFE.' IT IS FEARED THAT THE ERROR OF THIS MISPLACED CONFIDENCE WILL BECOME OBVIOUS ONLY IN RETROSPECT.

IN CONCLUSION, MR. CHAIRMAN, I WOULD LIKE TO STATE AGAIN THAT I BELIEVE THAT THIS BILL TAKES THE WRONG APPROACH TO RISK ASSESSMENT IF WHAT WE WANT IS FOR OUR SOCIETY TO REAP THE BENEFITS OF BETTER RISK ASSESSMENT WHILE AVOIDING SOME OF THE WORST ABUSES. IN ORDER TO PROVIDE A MORE POSITIVE CONTRIBUTION, A REVISED BILL SHOULD:

1) EMPHASIZE THE STRENGTHENING OF VERY DIFFERENT AREAS OF EXPERTISE THAT WOULD DO MORE TO OVERCOME THE MOST IMPORTANT EXISTING GAPS IN OUR KNOWLEDGE - EMPHASIZING RESEARCH IN THE SOCIAL AND BEHAVIORAL SCIENCES TO IMPROVE OUR UNDERSTANDING OF THE HUMAN BEHAVIORS THAT HAVE IMPORTANT IMPLICATIONS FOR MOST KINDS OF TECHNOLOGICAL RISKS, AND WORK IN ETHICS TO PROVIDE BETTER INSIGHT INTO

THE ETHICAL IMPLICATIONS OF TECHNOLOGIES THAT PROVIDE BENEFITS AND RISKS TO DIFFERENT PERSONS.

2) RATHER THAN TRYING TO DENY THAT REAL UNCERTAINTIES EXIST, SYSTEMATIC ANALYSIS SHOULD ATTEMPT TO PROVIDE POLICYMAKERS AND THE GENERAL PUBLIC WITH IMPROVED MEANS FOR MAKING GOOD DECISIONS EVEN IN THE FACE OF IRREDUCIBLE UNCERTAINTIES, GIVING A FAIR HEARING AND IMPROVED UNDERSTANDING TO THE DIFFERING (BUT OFTEN QUITE LEGITIMATE) VALUES UNDERLYING OPPOSING POINTS OF VIEW.

3) RATHER THAN ALWAYS TRYING TO DEVELOP "ALL OTHER FACTORS EQUAL," MATHEMATICALLY OBJECTIVE, PREDICTIONS AND ASSESSMENTS - ASSUMING AWAY "SURPRISES" IN AN EFFORT TO DEVELOP POINT ESTIMATES OF WHAT ARE SOMETIMES OPTIISTICALLY CALLED 'MOST LIKELY' OUTCOMES WE MAY NEED SYSTEMATIC EMPIRICAL RESEARCH ON THE FREQUENCY WITH WHICH SUCH SURPRISES OCCUR PARTICULARLY AS A RESULT OF HUMAN ACTIVITIES, AND WE MAY NEED TO DEVELOP PLANS AND PROCEDURES FOR DEALING WITH THE SURPRISES RATHER THEN NAIVELY HOPING THAT NO SUCH DISRUPTION WILL OCCUR.

4) NEW MECHANISMS NEED TO BE DEVELOPED TO ENCOURAGE SCIENTISTS TO PROVIDE TECHNICAL INPUT TO THE DECISION MAKING PROCESS WITHOUT ATTEMPTING TO USURP IT OR DISGUISE POLITICAL JUDGEMENTS AS SUPPOSEDLY SCIENTIFIC ONES.

Mr. **Scheuer**. Thank you very much. We appreciate your testimony, Congressman.

Congressman Mike Andrews of Texas.

Mr. **Andrews**. Thank you.

I just looked over your statement as you were reading it and I am just curious, do you believe we can write a bill that would be productive and be meaningful and meet the criteria that you suggest in your statement?

Mr. **Ottinger**. Well, I don't think you can eliminate the judgment factor in assessing risk, if that is what you are asking, but I do think you can systematize the means by which we get at making these value judgments, which I think in the last analysis really do have to be made by us rather than by scientists.

Mr. **Andrews**. I guess I am curious more than anything else. Do you think this can be done, can we do this, can this Congress accomplish this?

Mr. **Ottinger**. I think we can improve on the present process. So I do think legislation in this area is worth pursuing. I don't think you are going to arrive at any perfect solution, but then I don't think there is any perfect solution because the problem that we are facing today is we are able to quantify smaller and smaller and more and more minute, for example, particles of carcinogens and various chemical substances and foods that we eat, pesticides which are used to grow foods, the kind of assessments that have to be made become enormously difficult.

The costs that we are encountering in order to be able to cope with relatively minute risks are becoming matters of great concern. So that kind of judgments to which I refer in my statement are having to be made—I suppose that trying to make them in a systematic way and trying to articulate the criteria that we will use is a useful exercise, but, yes, I think it is a worthwhile pursuit.

Mr. ANDREWS. You mentioned—I think you made an excellent point in stating the need to bring in more disciplines and the lack thereof possibly in this legislation, and I wonder if you would expand on that because that has always seemed to me to be a problem that we have here in that is not utilizing enough disciplines in formulating some conclusions before we attempt to promulgate some type of legislation, and certainly in this area, it seems like we need to limit the number of disciplines but try to expand it as much as possible.

Mr. OTTINGER. Well, I think increasingly we are being placed in the most difficult kinds of situation virtually having to play God and make determinations that will certainly mean life and death to at least numbers of people in our society. To those decision, I think we ought not to bring only the hard sciences, but the soft sciences, which used to be in better repute than they are today, and I think they ought to be in better repute again, because we are dealing with just uniquely human factors here, and ethical considerations which are the most difficult to make.

I would think that bringing in the social sciences and how people behave in response to particular risks would be very, very helpful, very important in helping decisionmakers to make sound decisions.

Mr. ANDREWS. Thank you.

Thank you, Mr. Chairman.

Mr. SCHEUER. Congressman Tim Valentine.

Mr. VALENTINE. I don't have any questions.

Mr. SCHEUER. Congressman Don Ritter.

Mr. RITTER. I thank the chairman, and I thank my colleague from the Energy and Commerce Committee for his thoughtful statement.

The gentleman is——

Mr. OTTINGER. The gentleman is also on the Science Committee. I don't want to be shoved off before my time.

Mr. RITTER. I am on the committee for a day, due to the good graces of the chairman.

Mr. OTTINGER. I thought you were referring to this gentleman.

Mr. RITTER. Oh, yes. I would like to take up the comments of the gentleman from Texas, Mr. Andrews. He mentioned the insertion of different disciplines, and I noticed that that occurs in paragraph 3 of your statement, which talks about codifying this new area with a central board, and that deals with title II of the bill, which we, I believe on both sides, have seen fit to withdraw, that we are not at the present time looking at a central board of risk assessment. This was the so-called Jim Martin amendment, Martin of North Carolina, and we have, for some of the reasons the gentleman stated, removed that title as being perhaps premature.

In your statement you also talk about the impossibility of putting dollar signs on health and lives, and I agree. The interesting feature of this bill, and the way we have looked at the assessment of risk, and indeed this comparative assessment of risk, putting risks into some context with one another, if the assessments are performed in a reasonably similar fashion, tries to get away from the cost/benefit dilemma.

Those decisions are going to be made but they are not going to be made in this bill. Those decisions are very much social, political, judgmental decisions that do not impact on this bill. This bill attempts to separate out the assessing process from the managing process, but in that assessment process, the comparative phase is awfully important, because rather than try to put dollar signs on the costs to the Nation's health, with nuclear power—you mentioned the example of nuclear power and talked about Three Mile Island—if you compare the safety records in terms of hazards to workers or citizenry or what have you in a comparative assessment, one will find that a lot more people died last year in coal mine accidents.

I am not trying to make this the only comparison risk assessment around. That is one, say of looking at hazards, trying to put them in some perspective. The absolute value of the assessment is going to be very difficult to make a judgment on, but when you start putting these in context with one another, they become a little easier and the public can understand.

You mentioned new mechanisms are necessary to encourage scientists to provide technical inputs—this is your bottom line statement—to the decision making process without attempting to disguise political judgments as opposed to scientific ones, or somehow trying to substitute the judgments and biases of technicians, often not directly accountable to the general public.

This bill is drawn with that in mind. This bill simply provides assessment as a tool. I am not sure as to whether you made the interpretation that these assessments somehow stand in series with a decision process that you or we or our colleagues or the regulatory agency has to make, it is not intended, and we have excised out all of this idea of forced risk assessment.

Mr. OTTINGER. What bothers me is—let's take the Rasmusson report, which was presented to the public as a kind of bottom line on the safety of nuclear power. And it seems to me that just the quantification of the likelihood of particular kinds of accidents occurring isn't sufficient to make that judgment. One has to somehow or other weigh the magnitude of the accidents on which such a tiny risk ratio is applied.

The disruption to the communities that are involved even in a Three Mile Island accident, where meltdown finally did not occur and massive escape of radioactivity to the community, but there were tremendous costs. There were other kinds of costs. The actual costs of power all over the country went up and the feasibility of being able to install nuclear plants; the price people have to pay for electricity, all that came into play and aren't measured in the scientific risk assessment that was made by Mr. Rasmusson.

Mr. RITTER. From the health effect side it is not far off.

Mr. OTTINGER. What you have in nuclear power is a very tiny risk, as I was saying, of a huge catastrophe and what isn't measured is the depth of distress, suffering, death, that would occur if that minute risk comes into play. All that you have is an impression, since it is only one in so many million chances that the ultimate accident will occur, we didn't worry about it. It seems to me that that leaves a false impression.

Mr. SCHEUER. I might also say that the assumptions upon which we make these kind of risk assessments for nuclear accidents may be questionable. I think the assumptions may be that the technology is good, and that human beings may be competent, the human management. I think Three Mile Island proved the technology as excellent, but that the quality of the management of that technology was so abysmal, and the negligence and the stupidity and the carelessness and the gross incompetence was of such a level, such an abysmal level, that it seemed to me, that the people who might have made the original risk analysis of the potential for nuclear accidents never could have cranked into the process that degree of incompetence and negligence on the part of the managers of the high technology enterprise.

There would have to be an enormous outcry from the professional managers and engineers and utility companies all over the United States if they had dreamed of applying that kind of quality management in their risk assessment analysis.

Mr. OTTINGER. I fully agree and I do think that that is what is difficult about a purely scientific quantification of risk.

Mr. RITTER. Or the attempt thereof is simply a tool that is part and parcel of the larger universe of decisionmaking abilities. It is not meant to be a substitute for good human judgments, sound management practices. We have airliners falling out of the sky to this day, and no one is banning the airplane.

Mr. OTTINGER. Well, no one is banning nuclear power. I don't advocate that, but I do think that in making all risk assessments with which Government has to deal, one ought to include the possibilities of human error, human reaction to the kinds of risks which are being presented, and the social sciences, I think, can be a help in reaching that rather than just trying to present this as a physical scientific conclusion maybe with which policymakers can deal.

Maybe you are not turning over the decision ultimately solely to the hard scientists, but their pronouncements get enormous weight. It is like doctors. People tend to believe because of their authority and their distinction—I have seen it on this committee when Hans Beta comes before the committee, everybody kind of genuflects, all great scientists, and yet I think we mustn't be in a position where emminent scientists' or doctors' pronouncements are not subject to challenge by other disciplines.

Mr. RITTER. I submit the science input to the process here at the present time is extraordinarily limited, and all this bill tries to do is to up it just a little bit.

Mr. SCHEUER. Also, to provide some structure by which judgments are made.

All right, Congressman, we appreciate your testimony very, very much. You have certainly been a very constructive addition to our thinking. Thank you.

Mr. OTTINGER. Thank you for the opportunity to participate.

Mr. SCHEUER. We will now invite the first panel to come to the table.

Sanford Miller, Peter Preuss, Bernard Goldstein, and R. Leonard Vance. We are delighted to have you and this is a case where, on the subject of risk assessments, this panel constitutes a whole that is greater than the sum of the parts. There is a great totality of wisdom here. So, Mr. Miller, we will start out with you. We have 10 more witnesses this morning and we are running behind schedule, so we are going to ask each of you to sum up your testimony in 5 minutes and then after the 4 of you have testified—we have three panels—I am sure that Congressman Ritter and I and any of the other Members who are here will have some questions for you.

STATEMENTS OF DR. SANFORD MILLER, DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION; DR. BERNARD D. GOLDSTEIN, ASSISTANT ADMINISTRATOR FOR RESEARCH AND DEVELOPMENT, ENVIRONMENTAL PROTECTION AGENCY; DR. PETER W. PREUSS, ASSOCIATE EXECUTIVE DIRECTOR FOR HEALTH SCIENCES, CONSUMER PRODUCT SAFETY COMMISSION; AND DR. R. LEONARD VANCE, DIRECTOR, HEALTH STANDARDS PROGRAMS, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

Dr. MILLER. Thank you, Mr. Chairman, and with your permission, I would like to submit a more detailed statement for the record.

Mr. SCHEUER. All of your statements will be printed in full at the point in the record where you are called on to testify.

Dr. MILLER. Thank you.

Mr. SCHEUER. I would also ask unanimous consent that any members of the subcommittee, and of course Congressman Ritter, if they have any further questions after the panel is finished, can submit them in writing to the panel and we will hold the record open for 10 or 12 days to get answers.

I would also ask unanimous consent that any members of the subcommittee, or Congressman Ritter, can file statements at the end of each panel providing their assessments or any elaborations they want to make, remarks they want to make in answer to any of the points raised in the course of the testimony that time did not permit them to make. There being no objections to either of those two unanimous consents, it is so ordered.

Dr. Miller, please proceed as you wish for 5 minutes.

Dr. MILLER. Thank you, Mr. Chairman.

I am particularly pleased to testify on the subject of Congressman Ritter's bill, not only because quantitative risk assessment will play an increasingly important role in our decisionmaking, but also because the Food and Drug Administration was the first regulatory agency to propose its use. In 1973, FDA initially proposed to limit the concentration of residues of carcinogenic drugs used in food producing animals to a level that would produce a lifetime carcinogenic risk no greater than 1 in 100 million. Since then, while risk assessment techniques have gradually improved, the pressures on FDA and other regulatory agencies to deal with even lower concentrations of carcinogenic contaminants and impurities have more than kept pace.

FDA proposed to expand its use of risk assessment in April 1982 with our constituents policy in an effort to deal administratively with trace impurities in food and color additives in a rational and scientifically responsible manner.

And in June 1983, recognizing that our administrative discretion was too limited to deal with the full range of problems we face, FDA testified before the Senate Labor and Human Resources Committee, concerning the need for more statutory flexibility in dealing with carcinogenic additives under the so-called Delaney anticancer provisions of the Federal Food, Drug, and Cosmetic Act. Quantitative risk assessment is the principal analytical tool which can support more flexible risk management approaches.

While quantitative risk assessment is not yet a fully accurate predictor of carcinogenic risk, in appropriate circumstances—in particular with respect to impurities in food and color additives, animal drug residues and substances migrating to food from packaging materials—it can help FDA to distinguish between significant risks that we should be concerned about and risks that are insignificant to public health.

It has been used thus far only for estimating the worst use anticipated risk from low levels of added carcinogens in food, and only in those specific cases where the Delaney clause did not apply and where the data was sufficient to justify extrapolating quantitative estimates of human risk from animal data. This legal proscription against carcinogenic food and color additives at any level and weaknesses in toxicological and exposure data as well as dose extrapolation severely limit thus far our use of quantitative risk assessment.

On the other hand, the use of informal, semi-quantitative risk assessment procedures is, and has been for some time, an important element of our day to day decisionmaking. Virtually all approvals of drugs, devices, or biologicals require that we weigh the expected benefits against the anticipated side effects. In these cases, FDA ordinarily has access to human data and the problem of extrapolation from animals to humans does not arise. To the extent the data permit, we may attempt to quantify estimates of risk obtained from these studies in order to sharpen their precision or obtain a population risk estimate.

Nevertheless, when combined with other evidence and used in a conservative manner in a way that is not likely to understate the risk, it can be a valuable regulatory tool.

I would like to make a few comments about H.R. 4192. We recognize the importance of coordinating interagency risk assessment and management processes among those Federal agencies concerned with decisions related to the protection of human life, health and the environment. The FDA is currently a participating member of the Interagency Risk Management Council, which consists of representatives from each of the major health regulatory agencies.

We are also sensitive to the need for more explicit recognition of assumptions, uncertainties, and judgments inherent in some aspects of risk assessment and risk management decisions. At FDA, we pay special attention to the separation of scientific and policy groups within the agency. We regard this separation as vital to sound decisionmaking. We particularly agree with the provisions in H.R. 4192 which emphasize the need to facilitate public understanding of the nature of regulated risks and how they are quantified.

We agree with the purpose of title I of the bill and welcome the congressional initiative in highlighting its important goals. We believe that we can accomplish many if not all of its objectives under our current authority. For example, as mentioned above, we are participating in the Interagency Risk Management Council, which is already dealing with interagency risk assessment issues. We have also asked ourselves many of the same questions that are outlined in section 107 of the bill.

However, I hope we do not overemphasize the role of risk and risk assessment at these hearings and in our subsequent actions. It is because the degrees of risk acceptance by the public is not very well correlated with the magnitude of the risk even when it is accurately known; thus, the public will accept some things even though their use entails a risk, while it will reject other things with similar or lesser risks.

In conclusion, Mr. Chairman, we do support the basic purpose of title I of the bill. We believe that its goals and objectives are being integrated into the current ongoing efforts by the regulatory agencies. I believe that public confidence and trust is strengthened when Congress extends its support to interagency efforts at dealing with important public health problems.

Mr. Chairman, of course I would be pleased to answer any questions you or other members of the committee might have.

Thank you.

[The prepared statement of Dr. Miller follows:]

Statement by Sanford Miller, Ph.D., Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Public Health Service, Department of Health and Human Services

Mr. Chairman I welcome the opportunity to participate in this hearing on Title I, H.R. 4192, the "Risk Assessment Research and Demonstration Act of 1963." As requested by the Subcommittee, my testimony is limited to Title I of the bill. Before proceeding, however, I would note for the record that the Administration opposes Title II of H.R. 4192.

I am particularly pleased to testify on the subject of Congressman Ritter's bill not only because quantitative risk assessment will play an increasingly important role in our decisionmaking, but also because the Food and Drug Administration (FDA) was the first regulatory agency to propose its use. In 1973 FDA initially proposed to limit the concentration of residues of carcinogenic drugs used in food-producing animals to a level that would produce a lifetime carcinogenic risk no greater than one in one hundred million. Since then, while risk assessment techniques have gradually improved, the pressures on FDA and other regulatory agencies to deal with even lower concentrations of carcinogenic contaminants and impurities have more than kept pace. FDA proposed to expand its use of risk assessment in April 1982 with our "constituents policy" in an effort to deal administratively with trace impurities in food and color additives in a rational and scientifically responsible manner.

And in June of 1983, recognizing that our administrative discretion was too limited to deal with the full range of problems we face, FDA testified before the Senate Labor and Human Resources Committee, concerning the need for more statutory flexibility in dealing with carcinogenic additives under the so-called Delaney anticancer provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act. Quantitative risk assessment is the principal analytical tool which can support more flexible risk management approaches.

While quantitative risk assessment is not yet a fully accurate predictor of carcinogenic risk, in appropriate circumstances (in particular with respect to impurities in food and color additives, animal drug residues and substances migrating to food from packaging materials) it can help FDA to distinguish between significant risks that we should be concerned about and risks that are insignificant to public health. It has been used thus far only for estimating the "worst use" anticipated risk from low levels of added carcinogens in food, and only in those specific cases where the

Delaney clause did not apply and where the data was sufficient to justify extrapolating quantitative estimates of human risk from animal data. This legal proscription against carcinogenic food and color additives at any level and weaknesses in toxicological and exposure data as well as dose extrapolation severely limit thus far our use of quantitative risk assessment.

On the other hand, the use of informal, semi-quantitative risk assessment procedures is, and has been for some time, an important element of our day-to-day decisionmaking. Virtually all approvals of drugs, devices, or biologicals require that we weigh the expected benefits against the anticipated side effects. In these cases, FDA ordinarily has access to human data and the problem of extrapolation from animals to humans does not arise. To the extent the data permit, we may attempt to quantify estimates of risk obtained from these studies in order to sharpen their precision or obtain a population risk estimate.

Such applications are very specific to the substance or device at issue and depend very significantly on the nature of the product, its anticipated use, the susceptibility of the target population, the involvement of guidance from health professionals, and many other factors.

RISK ASSESSMENT—ITS VALUE TO FDA

Several foods contain either natural or synthetic carcinogens. A number of these carcinogens are now being detected in these foods because of new analytical techniques. These analytical techniques make it possible to detect carcinogens at the parts per billion level or lower as compared with the parts per million level possible a decade ago. However, the scientific basis of quantitative risk assessment at present is imperfect, particularly the extrapolation from animals to humans. Nevertheless, when combined with other evidence and used in a conservative manner chosen in a way that is not likely to understate the risk, it can be a valuable regulatory tool. It provides a measure of orderliness, openness and equity in the regulation of carcinogens. FDA has accepted it for a part, but not for the whole, of our regulatory effort and applies it cautiously and on a limited basis because of its scientific limitations as well as current legal proscriptions.

GENERAL AGREEMENT WITH THE PURPOSE OF H.R. 4192

The bill before us recognizes the potential of quantitative risk assessment as well as its many current limitations and proposes establishing a vehicle for improving the quality and uniformity of risk assessment activities throughout the health regulatory agencies. Certainly FDA agrees with the importance and desirability of these goals.

We recognize the importance of coordinating interagency risk assessment and management processes among those Federal agencies concerned with decisions related to the protection of human life, health and the environment. The FDA is currently a participating member of the Interagency Risk Management Council which consists of representatives from each of the major health regulatory agencies. One objective of this assessment approaches and in the management of risks that are unnecessary and that can be eliminated despite different statutory mandates. We are also sensitive to the need for more explicit recognition of assumptions, uncertainties, and judgments inherent in some aspects of risk assessment and risk management decisions. At FDA, we pay special attention to the separation of scientific and policy groups within the agency. We regard this separation as vital to sound decisionmaking. We particularly agree with the provisions in H.R. 4192 which emphasize the need to facilitate public understanding of the nature of regulated risks and how they are quantified.

SPECIFIC COMMENTS ON H.R. 4192

Title I of the bill before us would establish for the Federal health regulatory agencies a program to review the use of risk assessment by these agencies, to study its relationship to the regulatory process, to identify specific research needs, and to make recommendations to Congress aimed at the improvement of interagency use and coordination of risk assessment and risk regulation. The program would be conducted through interagency studies and demonstration projects under the supervision of a Presidentially designated agency or agencies. The designated coordinating agency would be required to report twice to Congress, initially within 12 months of enactment, and again in 30 months after the completion of the demonstration projects.

We agree with the purpose of Title I of the bill and welcome the Congressional initiative in highlighting its important goals. We believe that we can accomplish many if not all of its objectives under our current authority. For example, as mentioned above, we are participating in the Interagency Risk Management Council, which is already dealing with interagency risk assessment issues. This group represents most of the health regulatory agencies and the others mentioned in Sec. 105(b)(2) [Department of Energy (DOE), Department of Transportation (DT) and Nuclear Regulatory Commission (NRC)] could be added. We have also asked ourselves many of the same questions that are outlined in Sec. 107 of the bill as well as others that were not mentioned.

I would like to mention some of the specific objectives in the bill and discuss some thoughts that come to mind particularly with regard to FDA's experience with risk assessment.

The overall thrust of the bill and most of its specific provisions emphasize the role that risk and its measurement play in regulatory decisions. And the bill, rightly I think, emphasizes the difficulties in risk measurement, the need for better science to improve its reliability, and the difficulties of communicating arcane and seemingly inconsistent risk-based regulatory actions to the public.

However, I hope we do not overemphasize the role of risk and risk assessment at these hearings and in our subsequent actions. At least some of the current controversy over risk assessment derives not from the current inadequacies of risk assessment methodology, but over the acceptability of the regulatory consequences of risk assessment, even though such an assessment is conducted in a technically capable manner and applied in accord with the statute. However, the major reason that I urge some caution in this area is more fundamental.

It is because the degree of risk acceptance by the public is not very well correlated with the magnitude of the risk even when it is accurately known; thus the public will accept some things even though their use entails a risk while it will reject other things with similar or lesser risks.

In conclusion, Mr. Chairman, we do support the basic purpose of Title I of the bill. We believe that its goals and objectives are being integrated into the current ongoing efforts by the regulatory agencies. I believe that public confidence and trust is strengthened when Congress extends its support to interagency efforts at dealing with important public health problems.

I would be pleased to answer any questions that you, Mr. Chariman, or the other members of the Subcommittee may have.

Dr. SCHEUER. Thank your very much, Dr. Miller.

Now we will hear from Dr. Bernard Goldstein, Assistant Administrator for Research and Development of the EPA.

I don't wish to gavel you down in the middle of a sentence, but I do wish to tell you that this egg timer is serious and when you hear that bell, take another sentence or even two sentences if you have to, even with a couple of semicolons in the middle, as I sometimes do, but we are really fighting the time clock.

Thank you, Dr. Goldstein, please proceed.

Dr. GOLDSTEIN. Thank you, Mr. Chairman.

I am pleased to have the opportunity to appear before you today to discuss risk assessment and H.R. 4192, the Risk Analysis and Demonstration Act of 1983. Accompanying me today is Dr. Elizabeth Anderson, Director of the Office of Health and Environmental Assessment, the principal group doing risk assessment within the Office of Research and Development, and Dr. Richard Morgenstern, Director of Policy Analysis.

EPA supports the intent of H.R. 4291 and has—on its own—taken many steps which we believe follow the spirit of the bill. As requested by the subcommittee, my testimony is limited to title I of the bill. Before proceeding, however, I would note for the record that the administration opposes title II of H.R. 4192.

Mr. SCHEUER. Just to clarify things on behalf of my colleague, Don Ritter, title II is not a real subject of this hearing. They are not proposing title II. Their exclusive interest and concern is in title I. Let's not dilate on title I.

Dr. GOLDSTEIN. Thank you.

Administrator Ruckelshaus has made risk assessment one of his most important priorities. He has instructed our senior officials to do everything we can to improve the accuracy, consistency, and scientific quality of risk assessments, and to integrate them more effectively into the regulatory decision process.

In setting these priorities, Mr. Ruckelshaus shares the basic approach of the recent National Academy of Sciences report on this subject. That report emphasizes the need to distinguish risk assessment—the largely scientific process of determining the nature and extent of chemical risks—from risk management—the policy process of deciding what to do once risk has been determined to exist. Mr. Ruckelshaus has acknowledged the value of making this distinction between measuring and managing risk, and has committed the Agency to sharpen this distinction, as part of a general review of our regulatory process.

For the remainder of my remarks, I would like to emphasize what we are doing to pursue the scientific goals of H.R. 4192—rather than the risk management side of the equation. I will make only a few comments on risk management.

First, let me address the need for a coordinated Federal approach on risk assessment. Administrator Ruckelshaus has been working closely in recent months with the heads of most of the agencies mentioned within the scope of this bill: FDA, CPSC, OSHA, and FSIS/USDA. His goal has been to establish interagency cooperation on risk issues in general, and on risk assessment methods in particular. The result of his interactions with these agencies is the newly formed Interagency Risk Management Council.

The agency heads forming the Interagency Risk Management Council have met three times since December. They have commissioned three projects—cancer risk assessment, and strategies for biotechnology and formaldehyde—and are considering two others risk assessment for reproductive effects and strategies for solvents. Biotechnology is now being studied by a Cabinet level council, and the Interagency Risk Management Council expects to work with this group on the health and safety issues. We would expect that the subcommittee would be particularly interested in the Interagency Risk Management Council's plan to design interagency risk assessment guidelines for cancer risk assessment, since that effort is similar to one of the goals expressed in H.R. 4192.

The guideline development effort will take advantage of the OSTP document, "Chemical Carcinogens: Review of the Science and Its Associated Principles." The Interagency Risk Management Council is beginning the process of translating the OSTP principles into detailed operational guidance for the regulatory agencies to follow in conducting risk assessments. The Interagency Risk Management Council, in effect, is seeking to define criteria and standards to guide the development and use of risk assessment on an interagency scale, one of the stated objectives of H.R. 4192.

Writing interagency guidelines takes longer than writing them for a single agency's internal use. We at EPA have felt for some time that we should develop guidelines for assessing risks on a wider variety of health effects than simply cancer. To this end, we have developed and published several guidelines over the years. The agency recently embarked on a high priority effort to revise and expand all these guidelines.

We hope that, in the future, the Interagency Risk Management Council will take up these other guideline topics as well, and that the Government will ultimately reach agreement on consistent procedures for evaluating every catgegory of health risk that is of mutual regulatory interest.

Improving research in risk assessment methods is another concern of this bill. EPA is currently taking several initiatives related to this area.

One of the most significant may be an initiative just launched that establishes an intra-agency forum on EPA risk assessment matters. We are concerned that even when we have more and better risk assessment guidelines, there will always be a need to advance underlying scientific knowledge in each area.

It is entirely possible that, when substantial scientific differences of opinions occur, the forum will not be able to resolve every issue. Where appropriate, we will refer these issues to the outside scientific community to conduct research or otherwise provide guidance on difficult questions.

I hope this brief overview conveys to the subcommittee the depth of our commitment to making the concepts embodied in H.R. 4192 work in the real world.

Thank you.

[The prepared statement of Dr. Goldstein follows:]

Statement of Bernard D. Goldstein, Assistant Administrator for Research and Development, U.S. Environmental Protection Agency

Mr. Chairman and Members of the Subcommittee: I am pleased to have the opportunity to appear before you today to discuss risk assessment and H.R. 4192, the "Risk Assessment Research and Demonstration Act of 1983." Accompanying me today is Dr. Elizabeth Anderson, Director of the Office of Health and Environmental Assessment, the principal group doing risk assessment within the Office of Research and Development, and Dr. Richard Morgenstern, Director, Office of Policy Analysis.

EPA supports the intent of H.R. 4192 and has—on its own—taken many steps which we believe follow the spirit of the bill. As requested by the Subcommittee, my testimony is limited to Title I of the bill. Before proceeding, however, I would note for the record that the Administration opposes Title II of H.R. 4192.

Since taking office in June, 1983, Administrator Ruckelshaus has made risk assessment one of his most important priorities. He has instructed our senior officials to do everything we can to improve the accuracy, consistency, and scientific quality of risk assessments, and to integrate them more effectively into the regulatory decision process.

In setting these priorities, Mr. Ruckelshaus shares the basic approach of the recent National Academy of Science report on this subject "Risk Assessment in the Federal Government: Managing the Process." That report emphasizes the need to distinguish risk assessment—the largely scientific process of determining the nature and extent of chemical risks—from risk management—the policy process of deciding what to do once risk has been determined to exist. Mr. Ruckelshaus has acknowledged the value of making this distinction between measuring and managing risk, and has committed the Agency to sharpen this distinction, as part of a general review of our regulatory process.

Unfortunately, the history of this issue is noted for its semantic confusion. For instance, H.R. 4192 refers to risk assessment as a combination of risk analysis (analogous to the NAS definition of risk assessment) and risk evaluation (analogous to the NAS definition of risk management). We have been using the NAS definition since last year, and, if only for the sake of clarity, we suggest the Subcommittee use the NAS terms rather than the terms in the bill.

For the remainder of my remarks, I would like to emphasize what we are doing to pursue the scientific goals of H.R. 4192—rather than the risk managment side of the equation. I will make only a few comments on risk management.

H.R. 4192 would set up within the health and safety regulatory agencies of the Federal government a program of research and demonstration projects for a variety of purposes: (1) to improve the use of risk assessment within the agencies, (2) to develop a coordinated and systematic approach to the conduct and use of risk assessment, (3) to define criteria and standards to guide the development and use of risk assessments, (4) to identify research needed to improve the methods and use of risk assessment, (5) to coordinate the use of common research results and information, and, (6) to promote means for facilitating a public understanding of the nature of regulated risks and the means for their quantification. This program would be conducted within the existing Federal institutional framework under the coordination of a Presidentially designated agency or agencies. The Federal agencies participating in this research and demonstration program would include EPA, the Food and Drug Administration, the Occupational Safety and Health Administration, the Food Safety and Inspection Service of the Department of Agriculture, the Nuclear Regulatory Commission, the Consumer Product Safety Commission, and the Departments of Energy and Transportation.

Based on each agency's experience with these research and demonstration projects, the designated coordinating agency would be required to report within twelve months of enactment on: (1) a broad review of current Federal risk assessment activities, risk analysis research, and laws and regulations pertaining to use of risk assessment, (2) recommendations for a coordinating mechanism for transmitting or sharing research and results, and for increasing public awareness and understanding of risk, and, (3) a proposal for risk assessment demonstration projects. Each agency would also be required to perform a typical risk assessment within two years of enactment of the bill. The coordinating agency would then submit a second report thirty months from enactment, recommending: (1) areas for future research, (2) legislative and non-legislative changes for implementing and facilitating the use of risk assessment, (3) improved transfer of risk-related research and information, and (4) improved and increased public understanding and appreciation of risk and regulatory decisions.

I would like to summarize for the Subcommittee some of the initiatives we are already taking—initiatives which we believe will further the goals of H.R. 4192.

First, let me address the need for a coordinated Federal approach on risk assessment. Administrator Ruckelshaus has been working closely in recent months with the heads of most of the agencies mentioned within the scope of this bill: FDA, CPSC, OSHA, and FSIS/USDA. His goal has been to establish interagency cooperation on risk issues in general, and on risk assessment methods in particular. The result of his interactions with these agencies is the newly-formed interagency Risk Management Council.

The agency heads forming the IRMC have met three times since December. They have commissioned three projects (cancer risk assessment and strategies for biotechnoloy and formaldehyde) and are considering two others (risk assessment for reproductive effects, and strategies for solvents). Biotechnology is now being studied by a Cabinet-level council, and the IRMC expects to work with this group on the health and safety issues. We would expect that the Subcommittee would be particularly interested in the IRMC's plan to design interagency risk assessment guidelines for cancer risk assessment, since the effort is similar to one of the goals expressed in H.R. 4192.

The guideline development effort will take advantage of the OSTP document, "Chemical Carciogens: Review of the Science and Its Associated Principles" (May 22, 1984). This document provides a comprehensive and well-referenced review of current knowledge concerning the physical, chemical, and biological events that underlie the process of tumor development, and of the various methods appropriate for detecting and evaluating, in general terms, substances that may contribute to this process. It describes the scientific basis for inferring human risk from various types of scientific evidence. It also contains a set of principles intended to serve as a guide to Federal agencies for assessing cancer risk. The IRMC guidelines will derive from the OSTP document the analytic steps involved in performing a risk assessment, and specify how the analysis at each step is to be approached.

The IRMC is beginning the process of translating the OSTP principles into detailed operational guidance for the regulatory agencies to follow in conducting risk assessments. I believe that this work is an important step toward improving interagency consistency and scientific competency in risk assessment work. The IRMC also provides a forum for proposing cooperative research projects to improve the scientific basis of risk assessment. In addition, the IRMC is considering plans for similar work in the area of reproductive effects.

The IRMC, in effect, is seeking to "define criteria and standards to guide the development and use of risk assessment" on an interagency scale, one of the stated objectives of H.R. 4192.

Writing interagency guidelines takes longer than writing them for a single agency's internal use. We at EPA have felt for some time that we should develop guidelines for assessing risks on a wider variety of health effects than simply cancer. To this end, we have developed and published several guidelines over the years. These includes: guidelines for carcinogens (1976); guidelines for assessing risks for water pollutants (1980); proposed guidelines for mutagenicity (1980); and, draft guidelines for exposure assessment (1983). The Agency recently embarked on a high priority effort to revise and expand all these guidelines and develop new guidelines for teratogenicity and reproductive effects. These new and revised guidelines will be published in interim form, and should be available for public review and comment by mid-summer.

We hope that, in the future, the IRMC will take up these other guidelines topics, as well, and that the government will ultimately reach agreement on consistent procedures for evaluating every category of health risk that is of mutual regulatory interest. We do not believe that EPA's internal work will conflict with any future interagency efforts. Instead, it will be a springboard for these interagency activities. The important thing is that we have been broadening the scope of risk assessment beyond cancer evaluation to include other types of risks of serious public concern, to the fullest extent possible, given current scientific knowledge.

Improving research in risk assessment methods is another concern of this bill. EPA is currently taking several initiatives related to this area.

One of the most significant may be an initiative just launched that establishes a intra EPA Forum on risk assessment matters. We are concerned that—even when we have more and better risk assessment guidelines—there will always be a need to advance underlying scientific knowledge in each area and to evolve new approaches for risk assessment. The Forum will: (1) review specific risk assessments upon the request of the Administrator, Deputy Administrator, Assistant Administrators, or Regional Administrators; (2) provide a mechanism for interchange on science issues in risk assessment; (3) advise the Administrator and Deputy Administrator on precedent-setting cases and important risk assessment issues; and (4) recomment revisions or updates to the risk assessment guidelines, as appropriate. The Forum will also conduct an audit of a representative sample of risk assessments completed or underway to evaluate the consistency and quality of current Agency risk assessments.

It is entirely possible that, when substantial scientific differences of opinions occur, the Forum will not be able to resolve every issue. Where appropriate, we will refer these issues to the outside scientific community to conduct research or otherwise provide guidance on difficult questions.

I have left for last the matter of linking risk assessment to the regulatory process itself. This is the domain of risk management, and it is a subject of intense concern to the Agency.

It is also an area where we think each agency must make its own decisions in the light of its own statutes. EPA administers eight major statutes. In addition, we must carry out the requirements of Executive Order 12291, which requires an evaluation cf the costs and benefits of regulatory decisions. Our statutes vary considerably in the degree to which they require cost/benefit anslysis. Some require it. Some ignore it.

Whatever these variations, we feel we must be as explicit as possible about the factors considered in any decision affecting public risk. The public has a right to know exactly what factors or values we weigh in coming to a decision, and why we make the judgments we do. This means quantification of both the risks and the costs and benefits to the extent possible. Where quantification is not possible or appropriate, we must at least articulate the factors we are considering, in qualitative terms, if nothing else.

The aim of our approach to risk management is to provide a two-step process of regulatory evaluations, consistent with the recommendations in the NAS report. After we have assessed public risks, we then evaluate options for control—considering technical feasibility, social costs, economic costs, and the like. We can compare these options across media lines to identify the most important sources to control, and to develop a common basis for assessing benefits.

We have revised our regulatory development process to include a new regulatory options selection phase early in the decision process. This change will make explicit the entire range of options under consideration, giving the Administrator considerably more discretion to compare potential actions from one regulatory position to another. Second, we are also including, as a part of each regulatory package, a new form that specifically lays out all the key factors of risk management. Such a document would answer a number of important questions. What is the degree of risk we are trying to abate? What weight of evidence do we have to support our estimate? What level of risk do we expect to remain after the proposed regulation goes into effect? Who is affected? What are the costs of compliance?

Related to these two initiatives is a decision by the Deputy Administrator to create additional review staffs in each of the program offices to oversee these changes in the regulatory development process.

The Subcommittee's principal interest today is EPA's activities in risk assessment and risk management. I would like to link these processes to research activities within EPA. The risk assessment and the risk management process has an additional benefit to ORD. It is a very powerful tool for focusing on the crucial research needs for the problem at hand. At the time of the completion of the risk assessment, the Agency is in the best position to focus on which uncertainties are of greatest importance in the managing of risk. This permits focused cost-effective research to resolve these uncertainties for future decisions. It is of particular value where Congress has mandated that the risk assessment and/or risk management decision be reviewed, e.g., the National Ambient Air Quality Standards.

I hope this brief overview conveys to the Subcommittee the depth of our commitment to making the concepts embodied in H.R. 4192 work in the real world.

This concludes my prepared statement. We welcome the Subcommittee's interest in the issue of risk assessment and look forward to working with Members in expanding our knowledge and experience in this area. Dr. Anderson, Dr. Morgenstern, and I would be happy to answer any questions you have.

Mr. SCHEUER. All right, we will hear from Dr. Peter Preuss, Associate Executive Director for Health Sciences, Consumer Product Safety Commission.

Please proceed.

Dr. PREUSS. Thank you very much, Mr. Chairman.

Again, I will just summarize some of the major points in my statement, and I would like to begin by again stating our support for the objectives of this bill—that is, to improve the quality of the risk assessments that we do and thereby to improve the quality of the decisions that we make.

Quantitative risk assessment is a tool that is today used by all of the Federal regulatory agencies that deal with the issue of safety and health, and improvements in our analysis and assessments are certainly desirable. There is a great deal of current emphasis already on quantitative risk assessment, which I believe is the result of a steady evolutionary process that has taken place during the past decade. From a status a decade ago in which it was often an ornamental adjunct to the decisions, quantitative risk assessment today have become very often the anchor to which much of the other information and regulatory decisions are tied.

Although quantitative risk assessment has evolved to a new and central role in decisionmaking, it is important to understand that the large uncertainties inherent in quantitative risk assessment have not been appreciably reduced. Apparent advances in the way in which quantitative risk assessments are performed and presented, including the use of complex computer models, have moved quantitative risk assessments onto a perceived plane of precision and reliability. Sophisticated modeling techniques tend to give risk assessment the appearance of accuracy and, thus, contribute to increased emphasis on risk predictions.

But we must not forget, and cannot ignore, the many unknowns and uncertainties inherent in the process which render the risk assessment result neither demonstrably accurate nor reliable. However, it is precisely these unknowns and uncertainties which move us to join with the sponsors of this bill in working to improve this tool that we all use.

Mr. Chairman, there are three interrelated areas which influence our view of title I. First there is the global perspective, where advances in information on mechanisms, pharmacokinetics, and exposure assessment data bases show promise in improving the scientific bases for risk assessments.

Second, there is our own parochial perspective whereby we perceive that we are now in fact doing risk assessments in a manner very similar to that envisioned in the new demonstration project under title I.

Third, there have been some very significant multiagency activities relating to risk assessment that you have heard described, including:

No. 1, the work of the National Research Council of the National Academy of Sciences.

No. 2, the cancer principles recently published by OSTP and the science from which they evolve.

No. 3, the formation of the Interagency Risk Management Council, which provides an institutional framework for the continued development of improved risk assessments.

I have four specific recommendations for title I. Let me conclude with that simply.

No. 1, I think title I should specifically build on the National Academy of Sciences, the Office of Science and Technology Policy and Interagency Risk Management Council activities and not duplicate these efforts.

No. 2, title I should permit examination of retrospective risk assessment demonstration projects in cases where the agencies have already included the elements of section 107 in the risk assessments that they have done.

No. 3, alternatively, if title I is not modified to permit retrospective demonstration projects, then sufficient time should be allowed to enable participating agencies to conduct such a new project as part of its ongoing activities, rather than as an additional task.

No. 4, the Interagency Risk Management Council should be assigned the task of designating agencies and coordinating projects under title I. The establishment of another entity would, we believe, create a duplication of effort and ignore a significant existing resource.

With these changes, I am optimistic that title I can help us achieve further progress in improving our risk assessments and thereby our risk management decisions as well.

Again, I thank you for the opportunity to comment on H.R. 4192, and I would be pleased to answer any questions that you may have.

Thank you.

[The prepared statement of Dr. Preuss follows:]

STATEMENT OF PETER W. PREUSS, PH.D.; ASSOCIATE EXECUTIVE DIRECTOR FOR HEALTH SCIENCES, U.S. CONSUMER PRODUCT SAFETY COMMISSION

Mr. Chairman, Members of the Subcommittee—thank you for giving me this opportunity to comment on H.R. 4192. My name is Peter Preuss, and I am the Associate Executive Director for Heatlh Sciences at the U.S. Consumer Product Safety Commission. In this position I am responsible for the development of the Commission's risk analyses relating to chronic health hazards. As you requested in your letter to the Chairman of the Commission, I plan to focus my attention on Title I of the Bill.

Let me begin by stating my support for the objectives of this bill, i.e., to improve the quality of the risk assessments that we do, and thereby to improve the quality of the decisions that we make. Quantitative risk assessment is a tool that is today used by all of the federal regulatory agencies that deal with issues of safety and health, and improvements in our analyses and assessments are certainly desirable.

The current emphasis on risk assessment is the result of a steady evolutionary process that has taken place during the past decade. From a status in which it was often an ornamental adjunct to decision documents, quantitative risk assessment has today become the anchor to which much of the other information in a regulatory decision is tied. This evolution has come about, I believe, as a result of a number of different factors, including:

(1) Court decisions which have found that quantitative assessments are integral to the regulatory process;

(2) Congressional attention which has encouraged quantitation and the concept of comparative risk;

(3) Efforts by agencies of the Federal government and interagency groups to grapple with the issue and to define and describe how quantitative risk assessment is to be done;

(4) Increasing accent by recent administrations on the quantitation of the costs and benefits of regulation, and,

(5) Apparent advances in the art of risk assessment, such that, today, complex and difficult scientific issues appear to be resolvable through the assessment process.

Although quantitative risk assessment has evolved to a new and central role in decision making, it is important to understand that the large uncertainties inherent in quantitative risk assessment have not been appreciably reduced. Apparent advances in the way in which quantitative assessments are performed and presented, including the use of complex computer models, have moved quantitative risk assessments onto a perceived plane of precision and reliability. Sophisticated modeling techniques tend to give risk assessment the appearance of accuracy and, thus, contribute to increased emphasis on risk predictions. But we must not forget, and cannot ignore, the many unknowns and uncertainties inherent in the process which render the risk assessment result neither demonstrably accurate nor reliable. However, it is precisely these unknowns and uncertainties which move us to join with the sponsors of this Bill in working to improve this tool that we all use.

There are several ways in which the process of quantitative risk assessment can be improved. For one, we can work to improve the scientific bases upon which we rest our hazard assessments. Or, we can work to improve the sampling, analytical or modeling methodology upon which our exposure assessments are based. Or, we can work to improve the way in which the hazard and exposure information are combined to assess the probability and magnitude of the risks that people may face.

A fair amount of scientific research is underway to improve our hazard analyses. The areas of genetic and biochemical mechanisms and pharmacokinetics seem especially promising. The extrapolation of animal test data to humans will be more convincing with greater knowledge of the metabolic pathways of substances and their pharmacokinetics in various animal species. Tests are being developed which utilize animals believed to have defective genetic factors similar to defects found in humans predisposed to cancer. If our hypothesis is correct that altered DNA and the action of carcinogens are related, then a possible test system might be developed to detect persistent molecular damage after exposure to a suspect chemical. Other promising research areas include an improved understanding of factors controlling cellular differentiation, tests for chromosomal rearrangements and the development of systems to assay for substances that foster promotion and progression of the carcinogenic process.

The second area, that of exposure assessment, is also being investigated and studied. There is promise in the development of systematic approaches in monitoring studies, in mathematical modeling to extrapolate from representative systems to large populations and in improved and better validated data bases.

Improvements are also possible in the third area, that of combining hazard and exposure assessments to estimate risks, the area that this Bill addresses. Relatively little research is being done in this area currently, and consequently this Bill comes at a good time. I would suggest, however, that if we are to make progress in this area we must work within the existing scientific and political environment, rather than trying to develop additional environments outside of the present system.

What is the present system, then, and what is the environment in which we work? Our environment, at this time, is a delicate balance of forces among scientists in government, industry, academe, concerned citizens and administrators of regulatory agencies. As a result, during the past few years we have witnessed congressionally-mandated efforts to review the institution of risk assessment a the National Academy of Sciences, and new approaches to peer review of scientific documents; we have seen documents published dealing with the state-or-the-science of chemical carcinogens by the Office of Science and Technology Policy in the White House; we have held consensus conferences on specific chemicals such as formaldehyde; and we have helped prepare draft reports by the Ad Hoc Committee to Review Efforts of the National Toxicology Program; and, most recently, we have participated in the creation of the Interagency Risk Management Council by CPSC, EPA, FDA, FSIS and OSHA.

Within this environment, agencies such as ours have worked to meet the directions set out for us by Congress and interpreted for us by the courts. Our internal procedures, like those of other agencies, have been set and revised several times during the past ten years in light of scientific advances and political and judicial directives.

The Commission assesses risk for a number of reasons. First, the staff prepares a comprehensive review of all available informaiton, on a case-by-case basis, before making recommendations to the Commission about regulatory actions, such as labels, standards, or bans. Second, an abbreviated form of risk assessment is used, along with a number of other factors, to help us set priorities.

Once a decision has been made to seriously study a potentially toxic substance in a consumer product and before a regulatory decision can be made, the Commission is required by law to convene a Chronic Hazard Advisory Panel. A list of nominees is provided by the National Academy of Sciences, and the final selection is made by the Commissioners of the CPSC. The panel advises the Commission concerning the chronic hazards of cancer, birth defects, and gene mutations associated with chemicals in the consumer product under study. The Panel is required to submit a report that includes, if feasible, an estimate of the probable harm to human health that will result from the anticipated exposure.

The panel's report supplements the risk assessment done by the Commission staff, which includes: (1) the qualitative evaluation of the chemical's ability to produce adverse human health effects, (2) the likelihood of human exposure by type, magnitude and duration, (3) the mathematical modeling of the dose response relationship to estimate the magnitude of the risk or the upper bound on the magnitude of risk at a given dose level, and (4) the total evaluation of qualitative and quantitative information. This information is widely circulated for expert peer review and public comment.

Several years ago, we established an interdisciplinary group in our staff to review our chronic health hazard risk assessments. This group is expected to keep abreast of the latest developments in their fields and to utilize this new information in our risk assessments. They are encouraged to share information with their counterparts in other Federal agencies so as to be aware of improvements in risk assessment concepts and methodologies, and again, to apply that which they have learned.

After internal and external peer reviews, modifications and additional research are often appropriate. This process and the component risk assessment generally contain the elements to be included in a new "demonstration project" under Section 107 of Title I of H.R. 4192.

Returning once again to the previous theme, it is important to remember that these CPSC efforts take place within the framework of a much more comprehensive set of interagency activities. Some of these interagency activities are particularly important to the ultimate goals of this Bill and deserve some additional consideration.

In 1983 the Committee on the Institutional Means for Assessment of Risks to Public Health, of the Commission on Life Sciences of the National Research Council, analyzed risk assessment activities at four Federal regulatory agencies (CPSC, EPA, FDA, & OSHA) in their report entitled "Risk Assessment in the Federal Government: Managing the Process". Among the contributions of this unique report was the attempt to emphasize the need to separate the analytic functions of developing risk assessments from the regulatory functions of making policy decisions. An effort was made to provide standard definitions for the concepts inherent in risk assessment. In so doing, they began what I hope will be a common language in this area which will help us avoid misunderstandings in the future. Further, their report analyzes many of the institutional issues which Title I seeks to address.

A second, very significant effort dealing with risk assessment in the Federal government has just reached a milestone. On May 22, 1984 a report entitled "Chemical Carcinogens: A Review of the Science and Its Associated Principles" was published in the Federal Register for public comment. The report was released by the Office of Science and Technology Policy (OSTP) and culminated a two year effort by senior scientists from ten Federal health and safety agencies, including five of the seven agencies which would participate in the Title I demonstration projects. The purpose of the OSTP effort is twofold. First, to take a snapshot of the state-of-the-science of cancer risk assessment and, second, to set forth commonly held general principles which can serve as the basis for consistent regulatory cancer guidelines and policy withn individual agencies.

The document highlights advances in our understanding of the mechanism of carcinogenesis, and examines short-term testing and the relationship between genetic toxicity and carcinogenicity. It contains an evaluation of long-term animal tests and examines the current state of epidemiology as it related to human cancer. Exposure assessment developments and limitations are described, and the quantitative and qualitative cancer risk assessment processes are described.

The third significant program involving a number of Federal regulatory agencies working on improving risk assessments is the recently formed Interagency Risk Management Council. The Council consists of the heads of the Consumer Product Safety Commission, the Environmental Protection Agency, the Food and Drug Administration, the Food Safety and Inspection Service of the Department of Agriculture and the Occupational Safety and Health Administration. The Council meets regularly and recently has established two subgroups of particular interest to this Subcommittee. One is the Cancer Risk Assessment Task Group, which is expected to start with the OSTP general principles of cancer risk assessment and develop specific guidelines for cancer risk assessments. Second, the Council has just approved the formation of a Task Force to develop guidelines for reproductive health effects studies and risk assessments.

In summary, we see three interrelated areas which influence our view of title I. First, there is the global perspective, where advances in information on mechanisms, pharmacokinetics, and exposure assessment databases show promise in improving the scientific bases for risk assessments. Second, there is our own parochial perspective whereby we perceive that we are now in fact doing risk assessments in a manner very similar to that envisioned in the new demonstration project under Title I. Third, there have been some very significant multi-agency activities relating to risk assessment that you have heard described including: (1) the work of the National Research Council of the National Academy of Sciences, (2) the cancer principles recently published by OSTP and the science from which they evolve, and (3) the formation of the Interagency Risk Management Council, which provides an institutional framework for the continued development of improved risk assessments.

It is now the challenge for Title I to make the most of these advances and press forward. As I said before, we support Title I; however, this support is based on the premise that Title I will not require a duplication of those activities recently completed. It further presupposes that the implementation of Title I neither diminish nor delay progress of multiagency activities under way. With these general goals in mind, I have four specific recommendations for modification to Title I:

1. Title I should specifically build on the National Academy of Sciences, Office of Science and Technology Policy and Interagency Risk Management Council activities and not duplicate these efforts.
2. Title I should permit examination of retrospective risk assessment demonstration projects in cases where agencies have already included the elements of Section 107 in the risk assessments that they have done.
3. Alternatively, if Title I is not modified to permit retrospective demonstration projects, then sufficient time should be allowed to enable participating agencies to conduct such a new project as part of its on-going activities, rather than as an additional task.
4. The Interagency Risk Management Council should be assigned the task of designating agencies and coordinating projects under Title I. The establishment of another entity would, we believe, create a duplication of effort and ignore a significant existing resource.

With these changes, I am optimistic that Title I can help us achieve further progress in improving our risk assessments and thereby our risk management decisions as well.

Again I thank you for the opportunity to comment on H.R. 4192, and I would be pleased to answer any questions that you may have.

Mr. SCHEUER. Thank you very much, Dr. Preuss.

All right, now we will hear from R. Leonard Vance. Dr. R. Leonard Vance, Director of Health Safety Programs at OSHA—Occupational Safety and Health Administration.

Dr. VANCE. Thank you, Congressman, for the opportunity to discuss title I of H.R. 4192, which would establish demonstration risk assessment projects at eight designated Federal agencies.

On July 2, 1980, the U.S. Supreme Court, in *Industrial Union Department, AFL-CIO* v. *American Petroleum Institution et al*, 448 U.S. 607 (1980) ruled that section 3(8) of the 1970 Occupational Safety and Health Act requires that in regulating toxic substances, OSHA must find that the substance in question poses a significant health risk in the workplace. In this decision regarding OSHA's regulation of benzene, the court declared that the act requires a determination of significant risk and a finding that any new standard will significantly reduce or eliminate that risk. OSHA has interpreted the benzene decision to mean that risk assessment must be done, when possible, on standards issued under section 6(b)(5) of the act.

The type of risk assessment most often used by OSHA for developing health standards is a quantitative risk assessment. It attempts to predict the degree of occupational risk associated with a specific level of exposure to a toxic substance or physical hazard. This is done either through data from direct observation of the exposure level or by extrapolation, a statistical technique used to estimate risk at levels outside the range of observed exposure levels.

In performing quantitative risk assessment there are five factors that must be taken into account:

No. 1, the nature of the hazard which poses the risk.

No. 2, the quality of the data.

No. 3, the reasonableness of the risk assessment, which includes a description of the dose-response relationship.

No. 4, the statistical significance of the results.

No. 5, the significance of the risk presented by the hazard, including a description of the magnitude of the risk when considering other occupational risks.

I want to emphasize that the predictions of risk for this standard and other OSHA standards involve mathematical estimates with some inherent uncertainties. Risk assessments are estimates, not hard and fast predictions. Risk estimates represent probabilities that an event will occur based upon the limited data found in the studies.

For instance, a small study will have uncertainties associated with the statistical sampling of the study's exposed population compared to the unexposed population. In addition, assumptions are used to fill gaps in information, thereby creating other uncertainties.

During the past 12 months OSHA initiated and completed risk assessments for workplace exposure to asbestos, benzene, ethylene dibromide, and ethylene oxide.

In recent years, OSHA has taken steps to improve its capability to conduct risk assessments. An Office of Risk Assessment has been established in OSHA's Directorate of Health Standards Programs to ensure that risk assessment documents are prepared in a thorough and timely manner. The agency expects to add additional health scientists and statisticians to the existing office staff.

The Office of Risk Assessment is also responsible for interagency coordination. The Director of the Office recently spent 4 months working at the headquarters of the Environmental Protection Agency in order to understand EPA's risk assessment procedures.

OSHA provides drafts of its risk assessment documents to other Federal agencies, such as the Environmental Protection Agency and the National Institute for Occupational Safety and Health for review and comment, and in turn reviews drafts of risk assessment documents prepared by other regulatory agencies. Thus, valuable comments are exchanged. OSHA also participates in the interagency risk management council.

I wish to thank you, Mr. Chairman, for addressing this issue of risk assessment.

Mr. SCHEUER. Thank you very much.

[The prepared statement of Dr. Vance follows:]

STATEMENT OF R. LEONARD VANCE, DIRECTOR OF HEALTH STANDARDS PROGRAMS

Mr. Chairman and Members of the Subcommittee: I am Leonard Vance, Director of Health Standards for the Occupational Safety and Health Administration (OSHA). Thank you for the opportunity to discuss Title I of H.R. 4192, which would establish demonstration risk assessment projects at eight designated Federal Agencies under the supervision of an agency to be chosen by the President. Since I will not be discussing Title II of H.R. 4192, I would like to note for the record the Administration's opposition to that title.

Section 105 of H.R. 4192 would establish coordinated projects to improve the use of risk assessment within Federal regulatory agencies, including OSHA. The President would be required to designate an agency to coordinate the project. Within one year of enactment the coordinating agency would have to present a report to Congess that includes (a) a review of current risk assessments by designated agencies and of risk analysis research, (b) recommendations for a coordinating mechanism to facilitate sharing of research among Federal Agencies, and (c) a suggested proposal for a risk assessment demonstration project.

OSHA has no objection to the requirements of section 105. The information in the required report to Congress should increase awareness on the part of governmental decisionmakers and the general public concerning the different forms that risk analysis may take among various Federal agencies.

Section 106 would require the designated agencies, including OSHA, to recommend to the coordinating agency the research needed to meet the objectives set forth in section 105. OSHA agrees that the agencies involved with environmental and safety regulation should participate in formulating the risk assessment research required by the bill.

OSHA does not object to the requirement in section 107 for risk assessment demonstration projects by the Federal agencies designated in section 105, and particularly supports section 107(b) requiring that risk assessment studies shall be made available for peer review by the public and experts in the field. OSHA already employs such peer review for its risk assessment studies. For example, in developing an emergency standard for asbestos, OSHA asked scientists inside and outside the government to review and comment on its quantitative risk assessment. If the sponsors of this bill desire an adequate and realistic appraisal of the demonstration projects; peer review is essential.

It may be helpful to you to have me describe briefly the Agency's current risk assessment efforts. Let me begin by explaining the statutory basis for OSHA's use of risk assessment. Section 3(8) of the Occupational Safety and Health Act of 1970 (the Act) defines an occupational safety and health standard as a standard that is "reasonably necessary or appropriate to provide safe or healthful employment." Section 6(b)(5) fo the Act requires OSHA to consider the feasibility of its standards for toxic materials of harmful physical agents. The Act has been interpreted by the courts to require OSHA to consider the economic feasibility of its standards. This includes the costs of its regulations.

On July 2, 1980, the United States Supreme Court, in *Industrial Union Department, AFL-CIO* v. *American Petroleum Institute et al.*, 448 U.S. 607, ruled that section 3(8) requires that in regulating toxic substances, OSHA must find that the substance in question poses a significant health risk in the workplace. In this decision regarding OSHA's regulation of benzene, the court declared that the Act requires a determination of significant risk and a finding that any new standard can significantly reduce or eliminate that risk. OSHA has interpreted the benzene decision to mean that risk assessment must be done, when possible, on standards issued under section 6(b)(5) of the Act.

The Court indicated, however, that the significant risk determination is not a "mathematical straitjacket" and that OSHA is not required to support its finding of significant risk with anything approaching scientific certainty. The Supreme Court acknowledged that risk assessments, which may involve mathematical estimates with some inherent uncertainties, are nevertheless valid for demonstrating the existence of a significant risk.

In accordance with statutory language in the Act and the benzene decision, OSHA has developed an objective, rational approach to rulemaking which includes a four-step process for setting occupational safety and health standards. First, risk assessments are performed where possible and are considered with other relevant factors to determine whether the hazard to be regulated poses a significant risk to employees. In the second step, OSHA considers which, if any, of the proposed standards being considered to regulate a hazard will substantially reduce the risk. Next, OSHA looks at the best available data to develop the most protective approach to reduce the significant risk. The approach must be both technologically and economically feasible. Finally, in the fourth step, OSHA considers the most cost-effective way to achieve the objective.

The type of risk assessment most often used by OSHA for developing health standards is a quantitative risk assessment. It attempts to predict the degree of occupational risk associated with a specific level of exposure to a toxic substance or physical hazard. This is done either through data on direct observation of the exposure level or by extrapolation, a statistical technique used to estimate risk at levels outside the range of observed exposure levels.

In performing a quantitative risk assessment there are five factors that must be taken into account. I shall use OSHA's standard for inorganic arsenic to illustrate these considerations. They include: (1) The nature of the hazard which poses the risk. For example, in OSHA's risk assessment for inorganic arsenic, the Agency discusses the evidence of lung cancer in humans from arsenic exposure. (2) The quality of the data. In the arsenic standard this included discussion of the studies that were conducted which demonstrate the toxic effects of arsenic and the way in which the studies met established scientific protocol. (3) The reasonableness of the risk assessment, which includes a description of the dose-response relationship. In addressing workplace exposure to inorganic arsenic, OSHA predicted risk at the 10 ug/m3 permissible exposure limit (PEL). This was a dose level much lower than that actually seen in the employees studied. By using a mathematical model and certain biological assumptions, OSHA was able to extrapolate the risk from high to low levels of arsenic exposure. (4) The statistical significance of the results, and (5) the significance of the risk presented by the hazard, including a description of the magnitude of the risk when considering other occupational risks.

I want to emphasize that the predictions of risk for this standard and other OSHA standards involve mathematical estimates with some inherent uncertainties. Risk assessments are estimates, not hard and fast predictions. Risk estimates represent probabilities that the event will occur based upon the limited data found in the studies. For instance, a small study will have uncertainties associated with the statistical sampling of the study's exposed population compared to the unexposed population. In addition, assumptions are used to fill gaps in information, thereby creating other uncertainties. For example, a scaling factor has to be selected to convert animal studies to human estimates. Different scientists often choose different scaling factors. In the risk assessment done for the Inorganic Arsenic Standard, OSHA estimated risks to a factor of 10; that is, the lifetime cancer-risk under the new standard ranged from 2.2 to 29 excess deaths per 1,000 workers. Other risks assessments may have much greater uncertainties.

During the past twelve months OSHA initiated and completed risk assessments for workplace exposure to asbestos, benzene, ethylene dibromide, and ethylene oxide. As an integral part of OSHA's standards-setting process, risk assessment information generally emerges as part of that process along with various other kinds of data. OSHA staff, in developing a standard, usually do not focus solely on risk assessment but address risk along with a variety of other issues.

In recent years, OSHA has taken steps to improve its capability to conduct risk assessments. An Office of Risk Assessment has been established in OSHA's Directorate of Health Standards Programs to ensure that risk documents are prepared in a thorough and timely manner. This is the first time OSHA has devoted an office solely to preparation of risk assessments. The Agency expects to add additional health scientists and statisticians to the existing office staff. The Office of Risk Assessment is also responsible for interagency coordination. The Director of the Office recently spent four months working at the headquarters of the Environmental Protection Agency (EPA) in order to understand EPA's risk assessment procedures.

OSHA provides drafts of its risk assessment documents to other Federal agencies such as the Environental Protection Agency (EPA) and the National Institute for Occupational Safety and Health for review and comment, and in turn reviews drafts of risk assessment documents prepared by other regulatory agencies. Thus, valuable comments are exchanged. OSHA also participates in the Interagency Risk Management Council. This council includes the Environmental Protection Agency, OSHA, the Food and Drug Administration, the Consumer Product Safety Commission, and the Department of Agriculture. Items on its present agenda include development of a common approach to cancer risk assessment and to risk management of toxic substances for all the agencies concerned.

I wish to thank you, Mr. Chairman, for addressing the issue of risk assessment. As a responsible Federal regulatory agency, OSHA seeks to employ every tool at its command in developing safety and health standards. Risk assessment assists us in making better decisions about appropriate regulatory priorities. By providing a forum to discuss various approaches to risk assessment you have called public attention to this important subject. I cannot help but think that one result of your work will be improved regulatory efforts.

This concludes my prepared statement. I will be happy to answer any questions.

Mr. SCHEUER. Thank you very much.

I am sure that Congressman Ritter will have some questions. I have one or two. I hope that you would keep your answers to the questions as succinct as possible so that Don and I can get through the questions we have.

Dr. Goldstein, we have seen a great deal of research and risk assessments on acid rain. You know, it is of great concern to our country and even more of a greater concern to our neighbor to the north and to the Scandinavians. Many distinguished observers, both scientific observers and public policy people, feel that we haven't enough of a scientific basis to act, of a scientific data base to act.

The folks out in Boulder, CO, NCAR—National Council on Atmospheric Research—have told us for years we didn't know enough to act. Now they say we know enough to do the first sensible cost effective things. They don't say anymore that we don't have enough. I think there is an emerging consensus in the scientific community on acid rain that we don't have to wait until we know everything before we do anything.

Now, in the EPA Journal, on page 4, you were asked, "Is there a gap now between what we know and what we need to know?" Of course, there is a gap between what we know and what we need to know. We always need a more perfect data base. But in the exigencies of life as we know it, in our personal lives and our professional lives, we make all kinds of decisions everyday on imperfect data bases. We do the best we can but we have to make decisions.

You say, "When we talked about acid rain, the decision as to when we have enough information is a management decision, not a scientific decision." In your testimony today you said that you tried to crank into the regulatory process these risk assessment concepts.

Can you tell us what was the process by which you cranked into the regulatory mechanism your risk assessment perception and what was the result that flowed therefrom? Let us say in the years since Mr. Ruckelshaus has been heading up EPA.

Dr. GOLDSTEIN. Let me start by pointing out——

Mr. SCHEUER. Please make your answer much more succinct than the question.

Dr. GOLDSTEIN. All right. Point No. 1 is that the discussion is really risk assessments for health today and in fact we haven't done a formal risk assessment on the ecological effect. That is a somewhat different type of risk assessment, but we are talking about acid rain.

The next point to make is that the question of when is there enough data, I think gets into the management concept because it really requires a balancing of the costs—of the political costs, the dollar costs, all the other aspects that the Administrator must look at.

The third part of the answer would have to relate to what has happened since I got there, and what I have seen has been a clearcut demonstration of a will on the part of the leadership of the agency to separate the assessment aspects, the scientific aspects and the management aspects. I think it is working very well. We have a gap, we have far to go yet.

Mr. SCHEUER. I am desperately embarrassed at the prospect of flaunting my high school latin, but Juvenal, I know, when somebody was worried about their wife's fidelity, they established a guard system there, Juvenal wrote: Sed quis custodiet custodes?—But who will guard the guards? Now I think we are back to point of who will manage the managers.

Dr. GOLDSTEIN. In terms of the guarding of the guards on the assessment process, I think the more we can formalize this, the more that we can have clearcut guidelines, the easier it will be to see what the guards are doing. That is one of the aspects of this process that we support—the development of guidelines which are open and obvious to all.

Mr. SCHEUER. Thank you.

The bill calls for the President to designate an agency to coordinate these risk assessment projects. Would such a new program have any adverse effect or any effect, positive or negative, on the Interagency Risk Management Council or on other ongoing interagency coordination efforts? Any of you.

Dr. PREUSS. In my testimony, I recommended that this task be given over to the Interagency Risk Management Council, because of the fact that this new group, this Council, has started to look at many of the questions that this bill deals with. As Dr. Goldstein indicated in his testimony, there is a group working on cancer risk guidelines that I think will deal with much of this, and I think it is important to take advantage of this new effort rather than setting up an additional body that would just be another layer on top of it. I think we can do without an additional bureacracy.

Mr. SCHEUER. Well, how would the demonstration, sought to be carried out by this bill, differ from the formal quantitative risk assessments presently carried out by the agencies?

Dr. PREUSS. I think this bill raises a number of very interesting questions that need to be considered and not the least of which is taking a look at the risk assessments, and evaluating them, and seeing to what degree many of the basic scientific issues are dealt with in a consistent manner, and the degree to which those kinds of issues can be further resolved and the process improved.

I think that is something that is very important and something that I support quite wholeheartedly and something that I think this new Council could take on as an additional task if it were so directed.

Mr. SCHEUER. So you believe then that this bill, however its functions are carried out, whether by the Council, or by OMB, or whoever else the President might designate, let us assume, arguendo, by your Interagency Council, it would likely tell us or provide the opportunity for us to learn something about the risk assessment process that we don't already know, and further to refine and perfect the risk assessment process beyond its present stage?

Dr. PREUSS. I believe that what this bill calls for, in combination with the activities that are already underway through the Risk Management Council and some of the other groups that have been mentioned today, can indeed lead to an improvement in the way in which we do risk assessment. I feel very strongly that it should not be an additional burden, but should be a part of the process that is already going on.

Mr. SCHEUER. Thank you very much, Dr. Preuss.

Congressman Ritter.

Mr. RITTER. Thank you, Mr. Chairman, and I appreciate the testimony of the four gentlemen there because they have been doing the job and it is an interesting observation. I started with this idea from a legislative pursuit some almost 6 years ago and in the meantime it is gratifying to know that there are people out there who have actually be working in the trenches and doing the work. I like the idea of the Interagency Risk Management Council. We did not designate an agency, frankly, because we were unsure as to where precisely this kind of coordinating body would fit, and it seems to me that the system in operation has almost come up with that kind of a coordinating body, which I think will potentially remove some of the criticisms.

There has been a criticism in the first set of hearings, and I would like to get your comment on this, that by doing it within the framework of the executive agencies, such as yours, or the coordinating body of such an agency, this would add a polarization, a politicizing of the process, and that our intent to go forward with a refinement and betterment of risk assessments and a further understanding and a public understanding, and some comparative work in terms of putting risk and hazards into context for the public to better understand, that this would somehow suffer. And I would like comments from the individuals at the table because I think this is going to come up in later testimony. It has come up before, and I think it is something that I think it is going to have to deal with if it wants—and the chairman certainly does—if we want to move this bill forward.

Dr. Miller.

Dr. MILLER. There is always that danger of politicization of any activity that takes place in the Federal Government. It always exists. But I think that in this case the danger of establishing that adversarial relationship between the group responsible for coordinating the activities and the agencies responsible for actually doing the work, is much greater. The use of a group, such as an interagency committee, the Interagency Risk Management Council, removes that adversarial component. It is a creature of the agencies doing the work and they are providing the resources to do that kind of work. I think the possibilities of conflict are much, much greater if some other group was responsible for overseeing the activities.

One is always concerned about oversight. I might comment further to Mr. Scheuer that the people who watch the watchers are you gentlemen in the Congress, and in a situation like this where we are not performing correctly, I am quite sure we will hear about it as soon as possible. I am much more concerned about having, as Dr. Preuss said, another layer of bureaucracy to which we will all have to respond, and his suggestion about the Interagency Risk Management Council I think is a very wise one in this regard. There is no reason why the Council couldn't do virtually all the things that you propose in your bill.

Mr. SCHEUER. Just a brief remark about this word "politicization"—is that the word? Part of the risk assessment is cranking in political factors. That is certainly what our role is. Dick Ottinger thought that is a proper role. Risk management, risk evaluation, but not the risk assessments.

Dr. MILLER. That is correct. I think what we are all attempting to do is try to separate the science from the management components. It is in that management component that, of course, all the issues that Mr. Ottinger raised should be raised.

Mr. SCHEUER. That is where the politicization and assessment ought to take place. After Dr. Goldstein makes his best assessment of what kind of capital investment, based on current knowledge about acid rain, would be justified on a cost-benefit basis, on the basis of reasonableness, it is up to the manager to make decisions based on how severe partly—and I am not going to put words in your mouth, Dr. Goldstein, I will give you a chance to answer.

It seems to me what you are saying is the risk assessors are going to tell Mr. Ruckelshaus and the President, here are the costs of engaging in various levels of preventive action on acid rain, all the way from liming lakes, which is comparatively cheap, but not very effective, to scrubbers, which is quite a sustantial capital investment and has a much greater, long-term validity, and it is up to you to crank in whatever political assessments you wish to help make the decision down the pike as to what level of expenditures and capital investments are wise.

Dr. GOLDSTEIN. Well, the definition—we have a lot of problems with the semantics of the situation. The way we define risk assessment at EPA, we would not be discussing or providing information about capital costs. We are going to provide the information having to do with the number of lakes that are reversible or irreversibly damaged, the extent of damage to the forests, the extent of damage to fish, how the ecosystem is responding. The costs come out of the policymakers' side of the equation.

Mr. SCHEUER. That is management?

Dr. GOLDSTEIN. In the way we define it. We will be looking at the potential adverse effects and trying to quantitate those.

Mr. SCHEUER. It is not relevant to this hearing, but when will you have those assessments on acid rain?

Dr. GOLDSTEIN. We have quantitations right now. They have wide error bounds on them.

Mr. SCHEUER. What?

Dr. GOLDSTEIN. Error boundaries on them. Let me explain that. The extent of damage to the forest could be somewhere between zero and enormous, and if I can't tell the Administrator very specifically what the dangers are, then he has a right to make a decision that the costs are not worth dealing with. We are doing our best to narrow down the uncertainties so that our ecological-risk assessment is one that has a reasonably good impact to it. When we say so many trees or so many lakes, we will really know what we are talking about.

Mr. SCHEUER. When will that process be finished?

Dr. GOLDSTEIN. When will enough be enough? That is really the manager's call, not mine. We are going to narrow it down until we can't narrow it down any further.

Mr. SCHEUER. When will you be able to do that?

Dr. GOLDSTEIN. We are doing it right now. We are narrowing it down. We get more information every day on this subject.

Mr. SCHEUER. It is a continuing process?

OK, Congressman, excuse me. I didn't mean to interrupt you.

Mr. RITTER. I just had been requesting comments of the panelists on the use of the interagency review, risk-assessment review council, as the coordinating body for this bill.

Dr. PREUSS. Well, you understand where I stand on this, Mr. Ritter. The one other point I think that is important is that at this table you have the majority of the agencies in the Federal Government that have expertise in doing risk assessments, particularly if we include the research agencies that are part of the Department of Health and Human Services. And I think if we are going to work on improving the risk-assessment process, we have to build on that expertise as well. And again, that is why this Interagency Risk Management Council I think is a forum in which a lot of this can be brought together.

Mr. RITTER. I might add this: Some people say, why don't you just fund new work in risk assessment with various Federal agencies to have a greater amount of research going into the process, and that would be better than the bill. I submit that the two are not independent of each other, that when you provide an intellectual framework for research, then you are much more likely to have it attended to, and if people understand a little bit more about some of these more arcane ideas, and they get down to the understanding of even Congressmen, we will have something here.

And the overall, the final goal has got to be that the society has the ability to put hazards in better perspective than it has done in the past—perhaps than it is doing—and we can improve our ability here, and that is why this bill which deals with a legislative vehicle, contributes to your work in the executive branch, contributes to public understanding, and contributes to setting a special context.

Dr. Goldstein.

Dr. GOLDSTEIN. Basically, since we have been so instrumental in EPA in actively pursuing the idea of the Interagency Risk Management Council, I am sure there would be no objection to that being the leadership in this approach.

Dr. VANCE. OSHA has no problems with Interagency Risk Management Council carrying out that type of role. The IRMC is already in existence.

Mr. RITTER. What is your comment to the comments of the critics that somehow this could be politicized and we would then have destroyed the idea that assessments or analyses should be kept separate from the evaluation and management side?

Dr. VANCE. The principal politicization has to occur in the risk management rather than in the risk assessment side. The risk assessment side is far and away the less political of the two major activities involved with making societal decisions based on risk. The risk management decisions properly belong with Congress, with the policymakers and agencies. Congress delegates that authority to the policymakers.

Mr. RITTER. Can't this process be bastardized by, you know, pushing someone at the top of it who would then politicize the very mathematical, technical processes themselves?

Dr. VANCE. It is probably possible to politicize anything. It is less likely in the risk assessment process than in the risk management, but I doubt that there is any obscure, "arcane"—to use your word—area of astrophysics that it is not possible to get politics somehow in. The Interagency Risk Management Council in existence——

Mr. SCHEUER. IRMC, Risk Management Council?

Dr. VANCE. Yes; the interagency group is in existence. We are working together productively and amicably. We are dealing with many areas where politicization, I think, is less likely to be involved than it already is in the major risk management decisions, so I think the IRMC is a perfectly reasonable vehicle.

Mr. RITTER. IRMC really doesn't deal with the evaluation management of risk though.

Dr. VANCE. No, we are not risk managers.

Mr. RITTER. The title indicates that it does.

Mr. PREUSS. At the present time the effort of the group is focused on a number of areas of science, but I don't think they have ruled out at all the possibility of beginning to deal with risk management issues.

Dr. MILLER. There is an additional problem in attempting to coordinate risk management issues generally, and that is the statutes under which we operate—which often determines the actions we take—are different. So I am not so sure that in spite of the title, that the group will move in that direction, at least very quickly.

There are many problems at the moment in dealing with more objective components of risk assessments than moving to the more esoteric issues of risk management. Ultimately, I suppose they will get into issues as to what constitutes acceptable risk. I think that is some time down the line.

Dr. GOLDSTEIN. I would like to comment on the politicization. There is certainly an opportunity, as Dr. Vance said, to politicize anything. It is easy to do with risk assessment if one looks at one risk assessment for one compound in one situation at a time. However, one has guidelines which look generically across how you handle multiple pollutants in general situations, which will then guide the appropriate approach to how we do risk assessments in general.

It becomes difficult, much more difficult, to have value judgments take over where science ought to be. So that is why we strongly support a guidelines approach which will allow for consistency among the Federal agencies.

Mr. RITTER. If I understand you, that is really what I have been saying about this bill all along. Those who say that this is an attempt to politicize what is basically a scientific, technical intellectual process, at least used a tool as an input. I say it is exactly the opposite. What we are trying to do is keep it at a level, at a plane at which it is not politicized, and it is approaching a level of quality where it becomes acceptable within the system and within the legislature and out into the public in understanding these kinds of things.

Mr. SCHEUER. Congressman Lewis.

Mr. LEWIS. Thank you, Mr. Chairman.

I would like to ask Dr. Vance how do agencies currently set priorities for regulatory action?

Dr. VANCE. It varies from agency to agency. Each agency, of course, has its own organic statute. The techniques that are used at CPSC, EPA, FDA, may very well be dramatically different from that at OSHA. I can tell you how OSHA does it. I certainly can't speak for EPA, and EPA in particular has eight different major statutes, each of which has a different priority setting process. Would you like me to describe the OSHA process?

Mr. LEWIS. Give me how you prioritize.

Dr. VANCE. Congressman, we have a regulatory committee. We have a regulatory review committee at the agency which consists of all of the people who operate at my level, senior career service at the agency, who report to an advisor of the Assistant Secretary, who acts as the executive director at this committee. Any individual in the agency may bring an issue before this regulatory review committee for posting as a possible candidate for regulatory activity.

Basically, we have a round table discussion. If a consensus evolves that it is an appropriate candidate for regulatory activity, then that matter is taken to the Assistant Secretary. The Assistant Secretary makes all policy decisions, including all decisions as to whether or not to initiate the first man hour, I guess you would say just about, of regulatory activity on a particular compound or on a particular issue, if we are talking about a safety issue.

It is really very much a consensus development process and a matter of presenting pros and cons to the Assistant Secretary and having the Assistant Secretary make that call.

Mr. **Lewis**. How about EPA, do they essentially have the same kind of operation?

Dr. **Goldstein**. As Dr. Vance said, we have eight different statutes and we do it eight different ways, depending on the statutes we are dealing with. But whether we have the opportunity and the flexibility as much as Dr. Vance describes it——

Dr. **Preuss**. Our system is somewhat different. We have published in the Federal Register the kind of factors that we take into account in setting priorities, such as the nature of the risk, the severity of the risk, the degree of irreversibility, and so on. And during the past 2 years, we have in public meetings, the Commission has met to decide which areas will be priorities for the Commission and where we will concentrate our resources.

So that for this year, for example, they have chosen about a dozen such areas from dealing with all kinds of different hazards from consumer products which are in fact the major areas which we will pay attention to.

Dr. **Miller**. I can speak for the food regulatory activities of the agency, and in our case, our priorities are set on the degree to which we believe the public health is involved on a particular issue. Health issues dominate over economic issues and among health issues those that represent more acute problems receive higher priority than those that represent more chronic problems. We are faced on any particular day with issues that range from acute contamination of food as a result of accidents, to problems that are much more difficult and longstanding.

In our place we do this through a three step process. A single group, a separate group which identifies the hazard and determines the reliability of the data on which the hazard is existent; the second group that attempts to estimate the risk; and the third group that determines what action should be taken or what priority it should have.

Mr. **Lewis**. Thank you, Doctor.

Dr. Preuss, I have one final question. On page 5 of your testimony, you mentioned that an abbreviated form of risk assessment is used with a number of other factors to help set priorities. Why is the abbreviated form used?

Dr. **Pruess**. In general, Congressman, it is because we are at a much earlier stage of the process, and we don't have as much indepth information as we would normally have further along. When we come to the end of the work that we do, normally we have developed a great deal of toxicological information, a great deal of information regarding exposure, and we are able to put that together in a rather complete fashion. When we use this tool at the beginning of the process, very often the toxicological information is less than complete and we are estimating what the degree of exposure will be so that the process becomes much more abbreviated.

Mr. **Lewis**. Is there any great deal of cost differential between that and the formal risk management assessment?

Dr. **Preuss**. Yes, there is. When we do a large, full, comprehensive risk assessment, we usually have invested a fair amount of money in getting the kind of exposure information, for example, that is necessary, which will require either laboratory studies or field studies. We will have often tried to develop additional toxicological information, so that all feeds into a much more expensive piece than it would be at the beginning.

Mr. LEWIS. Thank you.

Thank you, Mr. Chairman.

Mr. SCHEUER. Thank you very much, gentlemen. It has been a most interesting panel and we appreciate all of your——

Mr. RITTER. If I may make one comment as a summary. There are some suggestions made in your respective testimonies which I think can strengthen the bill and would propose to do so with the chairman.

Mr. SCHEUER. That is what these hearings are all about, to educate us in how we can improve our product, and you have just heard from our colleague that you have done that, so you should feel very happy about the results of today's panel on which you contributed so much.

STATEMENTS OF FRANCES DUBROWSKI, ESQ., SENIOR STAFF ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL, ACCOMPANIED BY DR. KARIM AHMED; PAUL F. DEISLER, JR., VICE PRESIDENT, AMERICAN INDUSTRIAL HEALTH COUNCIL; DR. DAVID L. MALLINO, INDUSTRIAL UNION DEPARTMENT, ACCOMPANIED BY SHELDON SAMUELS; AND JOHN J. SHEEHAN, LEGISLATIVE DIRECTOR, UNITED STEELWORKERS OF AMERICA

Ms. DUBROWSKI. Thank you, Mr. Chairman, and members of the subcommittee.

Mr. SCHEUER. You have heard about our nefarious egg timer?

Ms. DUBROWSKI. Yes, sir.

Mr. SCHEUER. When you hear this egg timer, we want terror to be instilled in your veins, OK?

Ms. DUBROWSKI. In line with your instruction, I will very briefly summarize my testimony. With me is Dr. Karim Ahmed, our senior scientist and research director, who is an expert in risk assessment and has served on the National Academy of Sciences Committee on Risk in Decisionmaking.

Dr. Ahmed will explain why risk assessment is useful for priority setting but not decisionmaking, and why comparative risk assessment can be such a misleading exercise.

I would like to say very briefly that we are glad to see the subcommittee reexamining this bill because we believe the bill has serious problems. This is not simply a bill to improve the Government's use of science; it is a Trojan horse. Its goals are distinctly political. As written, the bill would serve at least two primary goals: increasing White House control over the scientific regulatory agencies and mobilizing public support for a rewrite of our existing health, safety, and environmental laws.

Mr. SCHEUER. I think my colleague is contemplating changing the locus of the process from the President's designation, which presumably would be OMB, to this interagency regulatory council. Would you be less concerned with that?

Ms. DUBROWSKI. We would strongly support that change, yes.

The other aspect of my testimony that I wanted to bring up is that this bill emphasizes recommendations for changes in legislation that would appear to be unnecessary since Congress is already reauthorizing most of the EPA-administered environmental laws unless—and here is where we become concerned—what is intended here is a different approach to these reauthorizations.

This bill has some serious definitional problems in that it uses the words "risk assessment," differently from the way it is normally used to include not only what people consider as risk assessment; that is, risk identification, but also the whole process of judging the symbol of those risks.

In many of the environmental laws, Congress has already made those balancing decisions and has removed the agencies prerogative to start exploring in those areas. So the bill, by focusing on a generic approach to the total process, would seem to ignore some of the important differences in environmental laws. With that as a brief summary——

Mr. RITTER. On this point, this bill was written prior to the National Academy of Sciences reported publication and I think we are perfectly willing to try and bring the definitional aspects of these terms, and as you know, they have been like pinning jello to the wall over the last several years.

We do believe in the Academy's approach to the definitional elements.

Ms. DUBROWSKI. That is another change which would strongly improve the bill. Still, we think the emphasis here should not be on rewriting existing laws and that appears to be part of the agenda of this bill. So that remains a concern.

With that, let me turn this over to Dr. Ahmed who would like to discuss why the use of comparative risk assessment will not improve, but will in fact, impair public understanding of risk.

Dr. AHMED. Thank you, Mr. Chairman. I think I will start off by first going over the question of definition of terms. I was interested to hear Congressman Ritter mention that this bill was written before the publication of the NAS report. That particular report, which was published last year, divides what was called the scientific or technical components of risk analysis from the so-called political judgment question into two terms: risk assessment and risk management.

The reason why there is so much confusion on these terms, a former committee on the National Academy of Sciences which I served on and Bill Ruckelshaus served on, used a different set of terminology like "risk assessment" or "risk analysis" in one sense and risk evaluations which are political or judgmental questions. This bill seems to reflect a lot of the language that came out of that earlier National Academy of Science Report.

The point I think Fran just made is an important one that you should have one set of definitions. The definition that is now used by the Federal agencies is the one inherent in the red cover NAS report before you.

Before I go into comparative risk assessment, let me mention briefly what this particular process we are talking about, risk assessment, is as identified in the report. It has four components. One is the risk identification process, which entails determination on essentially a qualitative basis of whether a substance or compound poses a hazard or risk.

Second, is exposure assessment, a very important step which is an attempt to identify individuals at risk as well as magnitude, type and duration of risk. Third is dose-response assessments which is to see the relationship, using models between exposure levels and health effects. And finally, what we have all been talking about all morning is risk characterization or quantitative risk assessment, which is an integration of the first three steps into some form of estimate of the risk of a given substance or compound.

I would like to stress this point very importantly. We have been focusing on the concept of quantitative risk assessment as if it were one aspect, which is not true. Risk assessment entails a much broader array of studies and scientific evaluations including conducting animal tests, doing epidemiological tests, figuring out what the exposure levels are and so on.

And I think the way the National Academy of Sciences has defined the term, "risk assessment," has to be seen in that broader perspective. Many speakers this morning talked about the problems concerning determining quantitative risk estimates because of the inherent problems about using these models and so on.

First of all, we are using, the many times when we talk about health risk questions, animal studies. We are not using human studies or clinical studies. This poses a problem about extrapolating information. On the other hand, in the risk characterization step, we have to use simplifying assumptions and use statistical and mathematical models which can give us some idea of the relative potency of a substance.

I would like to refer to statements made in the recent OSTP draft document published a few weeks ago in the Federal Register where they mentioned risk assessment processes should not be viewed as strictly scientific in the usual sense of the word. Instead, risk assessment involves a complex blend of current scientific data, reasonable assumptions and scientific judgments that permit decisions to be made in the absence of complete information.

I don't think I will spend much time talking about the various problems associated with quantitative risk assessment because many of the earlier speakers alluded to this particular point. However, I have a problem. I would like to talk about comparative risk assessment implicit in the present bill.

It has, I believe, a very limited scope, particularly with respect to public understanding of risk. One cannot, and should not, compare mortality risks from automobile accidents or home fires with carcinogenic risks from ingesting a food-additive or pesticide.

In the first instance, we are using actuarial data, for example, insurance companies, to give us pretty hard estimates of risk. On the other hand, when we look at carcinogenic risk, we are looking at very uncertain types of estimates and we are talking about injuries. When we compare injuries of 1 in 1 million or 1 in 1,000 and compare it to risk, it is a highly misleading exercise.

I submit that it is not comparing apples and oranges; it is not even comparing fruits. To the extent that the bill requires that Federal agencies get involved in comparative risk assessment as a way of informing the public, I think it is a very misleading exercise. I want to stress this point. Let me summarize my testimony by making two conclusions.

One, risk assessment is not merely an exercise of generating some simple quantitative risk estimate based on incomplete and often marginal data base, but it is a more comprehensive array of experimental studies, each needed with quality assurance and reliability to make a reasonable risk estimate which could provide decisionmakers with a rough idea about the risk of a substance or compound; and two, that risk assessment methods, while providing decisionmakers with guidelines to policy options, are too complex and too varied to have a standard basis for comparing the different types of risk an individual may be exposed to.

Thus the bill's emphasis on comparative risk assessment is misguided.

[The prepared statements of Ms. Dubrowski and Dr. Ahmed follow:]

TESTIMONY OF

FRANCES DUBROWSKI, SENIOR ATTORNEY

AND

DR. KARIM AHMED, SENIOR SCIENTIST

NATURAL RESOURCES DEFENSE COUNCIL

BEFORE THE

NATURAL RESOURCES, AGRICULTURE RESEARCH AND ENVIRONMENT SUBCOMMITTEE

OF THE

HOUSE SCIENCE AND TECHNOLOGY COMMITTEE

JUNE 5, 1984

TESTIMONY OF FRANCES DUBROWSKI

Mr. Chairman and members of the Subcommittee, it is a pleasure to be invited to testify before you. Accompanying me is Dr. Karim Ahmed, our senior scientist and research director. Dr. Ahmed is an expert in risk assessment and has served on the National Academy of Science's Committee on Risk in Decision-making.

We are pleased that the Subcommittee has taken this opportunity to re-examine H.R. 4192 because we believe that there are serious problems with the bill. Our testimony today will focus on two principal themes. First, H.R. 4192 is not simply a bill to improve the government's use of science; instead, its goals are distinctly political. Second, to the extent that H.R. 4192 alters the government's use of science in regulatory decision-making, it is likely to do so in a way which will impair, not improve, policy selection and obfuscate, not enhance, public understanding of the risks involved.

H. R. 4192 is a Trojan horse. It masquerades as an exercise in science, but its hidden agenda is blatantly political. Its core provisions serve two primary goals: increasing White House control over the scientific regulatory agencies and mobilizing public support to rewrite the current health, safety, and environmental laws.

For example, Section 105(c) of the bill places implementation of the bill under the control of a "coordinating agency" to be designated by the President. Earlier versions of the bill had explicitly named OMB as coordinator, but this was changed due to the obviously controversial nature of such a designation. Still, there is nothing in the bill to prevent the President from choosing OMB, some other White House entity (such as OSTP), or the agency most amenable to the Administration's own polical agenda as the coordinator.

Once in charge, the coordinating agency assumes control over key aspects of decision-making in all scientific regulatory agencies. It has the apparently unfettered right to select the regulatory decisions which will become involved in the risk assessment demonstration projects. It has an undefined and potentially quite powerful role "coordinating" the conduct of each risk assessment demonstration project. It has a broad-ranging mandate to review all current risk assessments and their use in decision-making. It has the right to determine research priorities, regardless of how these priorities fit into the overall agency budget and agenda. It has the mandate--despite the potential absence of any expertise or background in the history of a particular regulatory program--to analyze where risk assessment is "required, encouraged, limited, or prohibited by current law, regulation, or practice" and to recommend changes in the legislation. And it alone, without so much as a requirement for agency review, prepares the reports to Congress on the results of the risk assessment demonstration projects and their import for each regulatory agency's authorizing legislation.

It is not quite clear why Congress would want to transfer this much power over the scientific regulatory agencies to the White House--or if it has even considered this bill in sufficient depth to understand that a transfer of power is at stake, but it should be quite clear that such a transfer of power is a political, not scientific exercise.

The limited nature of today's hearings prevents us from discussing in detail why this is a bad idea, but other House Committees have developed extensive hearing records on the abuses that have occurred when White House officials assumed control over the regulatory agencies charged with responsibility for administering the nation's health, safety, and environmental laws. See, for example, the initial hearing record on Executive Order 12291 compiled by the House Oversight and Investigations Subcommittee of the Energy and Commerce Committee and the extensive hearing record on proposed Regulatory Reform legislation compiled by the Administrative Law and Governmental Relations Subcommittee of the House Judiciary Committee. These records show that government functions best when control over decision-making is left in the hands of the agency charged by Congress with responsibility for administering a regulatory program. Since H.R. 4192 potentially removes EPA's control over key aspects of any risk assessment study, it flies in the face of lessons already learned from E.O. 12291 and other "regulatory reform" proposals.

The political nature of this bill is also manifested by its focus on potential changes to existing health, safety and environmental laws. For example, Section 107, the core provision of the bill, mandates risk assessment demonstration projects containing 9 key elements. Five of these elements require the White House-designated coordinating agency to identify and recommend changes to existing statutes or to develop information whose only purpose appears to be mobilizing public support for changes to existing laws.*

The coordinating agency is invited--indeed, mandated--to recommend changes to existing health and safety legislation, §108(a)(4), and one of the express objectives of the bill is to promote public awareness of, and implicitly reassessment of, risk-controlling statutes through the use of comparative risk assessment, §§102(a)(7) and (8) and 105(a)(6) and (7). Again, this is a political, not scientific, exercise.

It would also appear to be an unnecessary exercise as Congress is now in the process of reauthorizing most of the EPA-administered environmental statutes unless--and here lies our concern--it is intended to leverage a different approach to these reauthorizations. H.R. 4192 does, in fact, stress a generic approach to risk-management legislation and policy, an approach we view as unwise given the important differences in the policy or science underlying different enviromental laws. In addition, H.R. 4192 would engage agencies in the business of promoting comparative risk assessment to the public. This, too, is unwise because it will tend to emphasize a single estimate of risk, ignoring large uncertainties in the data, and because it will tend to suggest that very different types of risk are similar. Thus, H.R. 4192 will be counterproductive to its expressed goal of "improving knowledge and use of risk assessment." Dr. Ahmed will elaborate in more detail on why risk assessment necessarily involves such large uncertainties and why comparative risk assessment is misleading. In conclusion, I would simply like to urge the Committee not to move this bill.

---

*The coordinating agency must identify statutory constraints on risk assessment, §107(a)(5); identify specific tradeoffs in the risk assessment, §107(a)(6); suggest changes to the statute, §107(a)(7); show how comparative risk assessment can be used to alter public perception, §107(a)(8); and delineate information which could be used to reassess the sharing of risks and benefits under current law and policy, §107(a)(9).

TESTIMONY OF DR. KARIM AHMED

As defined in the bill, "risk assessment" is divided into two components, namely risk analysis and risk evaluation. Risk analysis (usually called "risk assessment" by others) deals with the technical or scientific aspects of risk assessment, and risk evaluation considers the policy or political nature of risk in the context of regulatory decision-making. The term "risk evaluation" as used here has also been termed "risk management" by others.

Let us examine the concept of risk assessment as it has been delineated by recent attempts at defining the term more precisely. The National Academy of Science's Committee on the Institutional Means for Assessment of Risks to Public Health published a study last year which identified four components of any risk assessment process: (i) hazard identification, which entails a determination on an essentially qualitative basis of whether a substance or compound poses a hazard or risk, (ii) exposure assessment, which is an attempt to identify individuals at risk as well as the magnitude, type and duration of the risk,(iii) dose-response assessment, which is an exercise, using mathematical models, to derive a relationship between exposure levels and health effects, and (iv) risk characterization, which is an integration of the first three steps into a quantitative estimate of the risk of a given substance or compound. It should be stated that the NAS report focused its attention on health risks and did not examine the methods or approaches used for estimating risks to the biota or the natural environment.

It can be seen from the above that risk assessment encompasses an entire array of data production and data analysis. Thus, by the above definition, risk assessment is a composite of studies which determine both the hazards associated with a substance using experimental approaches and the risk estimates which are based on the experimental data. The generation of hazard information may include short and long-term animal toxicity tests, epidemiological studies, clinical tests, measurement of ambient exposure levels, chemical fate and transport characterization, and other laboratory and field experiments.

As defined by the present bill, risk assessment is viewed in the narrow context of what the NAS report defined as only one step in the entire risk assessment process, namely, step (iv) or "risk characterization". This step is also known in the trade as "quantitative risk assessment," (QRA), which as mentioned earlier is an attempt by agencies and others to generate some rough estimate of the risk which may be posed by a given substance or compound. The emphasis is on the word "rough," since QRA at present is more an art than a science, more dependent on the judgment of the assessor than on any well-defined or codified set of principles. This point cannot be stressed enough.

Let us state the reasons why QRA is unlikely to provide more than a rough guide to decision-making or priority-setting for an agency. In most instances, knowledge about the hazard of a substance is derived from animal tests. The results of these bioassays, particularly those related to evaluating chronic effects such as carcinogenic or mutagenic effects, can only be viewed as indicative of a potential human risk. In other words, animals serve as adequate human surrogates only in a qualitative sense. Positive adverse responses in animals clearly indicate similar potential effects on humans. That is as far as we can all agree.

On the other hand, we are forced to use simplifying assumptions and choose statistical and mathematical models which give us some idea of what the relative potency of the substance may be, but do not really tell us about the true magnitude of risk to a human population. For example, cancer risk estimates may differ by as much as six orders of magnitude (i.e., a million fold) depending on the models we choose and the assumptions we make as to a substance's mode of interaction with biological organisms. As the most recent Office of Science and Technology Policy review draft document on chemical carcinogens (published on May 22, 1984; 49 F.R. 21594) states:

> "[Risk] assessment process should not be viewed as strictly "scientific" in the usual sense of the word. Instead, risk assessment involves a complex blend of current scientific data, reasonable assumptions and scientific judgments that permit decisions to be made in the absence of complete information."

The OSTP document also identified a number of built-in uncertainties in the present methodologies of risk assessment, and cautioned decision-makers on relying too heavily on risk estimates derived from current state-of-the-art models and approaches.

Another step in the risk assessment process which is at present replete with uncertainties is in the estimation of exposure of an individual or a population to a given substance. To a large extent, this is due to the enormous data gap on the actual exposure levels to which an individual is exposed both in the ambient environment and in specific confined areas, such as indoor air or the workplace environment. In addition, the methods used to determine exposure levels only look at one media at a time, and risk estimates derived from this data base can be misleading or, at best, limited.

For example, recent carcinogenic risk estimates of EDB which were carried out by the federal EPA only accounted for EDB present in grain and grain products. Unlike early risk estimates, it ignored the additional contribution of risk from the presence of EDB in citrus or tropical fruits. None of the studies published to date, except the New York State Department of Health risk assessment study, even looked at the considerable amount of EDB present in the ambient air. Thus, again depending on the exposure data base we choose and the number of different exposure sources we include in our analysis, we could arrive at quite marked differences in carcinogenic risk estimates. In our analysis of the EDB risk estimates, using essentially similar mathematical extrapolation methods, different risk estimates varied by as much as 3 to 4 orders of magnitude, mainly on the exposure assessments which were included in the studies.

Another element in risk analysis is the types and varieties of hazards an individual may face in his/her daily life. Risk assessment methodologies for carcinogenic effects have now reached a stage where there is beginning to be agreement on certain principles and limitations, as is seen in the recent OSTP draft document. On the other hand, we have no such understanding on other health effects, such as reproductive effects, neurobehavioral effects, or acute and chronic respiratory disorders from air pollutants, to name a few.

In fact, risk assessment is a generic term that is also used in other fields of interest. How, for example, does one conduct a risk assessment study of a genetically engineered organism, or how does one assess the long-term risk of atmospheric CO_2 buildup or stratospheric ozone depletion? Each problem has different sets of scientific data bases and methodologies, with experts from very different disciplines. None of these individuals have spelled out their methods for risk assessment nor should they be forced by some single government entity to follow the path that others have chosen. This is because the environmental issues are not comparable, and risk estimates derived for each effect are based on an approach or understanding of the underlying scientific data quite at variance from the other. Atmospheric scientists and modellers do not look at the same type of data nor use the same methods of analysis as do toxicologists or pathologists looking at animal organisms.

The concept of comparative risk analysis, as implied in the present bill, has, at best, very limited scope, particularly with respect to public understanding of risk. [One cannot, and should not, compare mortality risks from automobile accidents or home fires with carcinogenic risks from ingesting a food-additive or pesticide.] ① In the former instance, relatively accurate and reliable risks can be derived by using actuarial data from insurance companies. On the other hand, cancer risk estimates are rarely based on epidemiological data (except for tobacco smoking, asbestos and a few occupational substances), and therefore have larger inherent uncertainties associated with them. To state that a cancer risk is only one-in-a-million or one-in-a-thousand and then compare that risk to injury in a car accident or a home fire is a highly misleading exercise. It is not merely comparing apples and oranges; it is not even comparing fruits.

Moreover, even if one accepted a carcinogenic risk for a given substance to be small (say 1 in 100,000), it must be seen in the context of other equally small carcinogenic risks from other potential carcinogens. Thus, 100 such substances, each with a 1 in 100,000 risk estimate, would amount to a 1 in 1,000 risk, assuming we are exposed to them in similar amounts. This is merely the additive effect of several carcinogens and does not consider potential synergistic effects which are known to occur for certain combinations of cancer-causing substances, such as tobacco smoke and asbestos. Thus, for a carcinogen, so called "de-minimus" risks are also misleading, for they estimate the risk of each separate substance and do not consider the additional or synergistic effects of the complex of substances to which we are exposed daily.

Conclusion

The main conclusions that can be reached from the above are two-fold: (i) risk assessment is not merely an exercise of generating some simple quantitative risk estimate based on an incomplete and often marginal data base, but is a more comprehensive array of experimental studies, each needed (with quality assurance and reliability) to make a reasonable risk estimate which could provide decision-makers with a rough idea about the risk a substance or compound may pose to a human population, and (ii) that risk assessment methodologies today, while providing decision-makers with guidelines as to policy options, are too complex and too varied to have a standard basis for comparing the different types of risk an individual may be exposed to. Thus, the bill's emphasis on comparative risk assessment is misguided.

Mrs. SCHNEIDER. Thank you very much. I would like to welcome Dr. Deisler. And if you would please maintain your testimony to the 5-minute time limit, because we think that all of your testimony will be incorporated into the record, but we really would like to have the opportunity to ask you some questions.

They are putting the timer on now.

Dr. DEISLER. Thank you very much. I am here this morning representing the American Industrial Health Council, although I am employed by Shell Oil Co.

I might start first by saying that the council itself is a very broadbased organization. It does not act as a spokesman for any particular commodity, but its focus has been primarily on the role of science and the identification and control of chronic health hazards, particularly potential carcinogens and in that respect I think much of what it has been doing is the kind of thing one finds in the bill under discussion.

The council believes that scientific risk assessment and therefore science, plays a critical role in achievement of risk assessment. AIHC therefore supports the intent of title 1 of H.R. 4192. We also would like to comment that the definitional problems that have been alluded to. We support this concern and in fact Dr. Joseph Rodricks in his testimony on May 17 discussed the definitions—and we support his views.

The amount of data that is available of various types on health effects is enormous and it includes not only the man-made chemicals, but on many thousands of natural chemicals. One can find positive effects even in things such as oxygen; the fact is, then, that a spectacularly increasing amount of data varies in quality and it varies greatly in relevance to the human situation.

It is therefore critical to evaluate the data and characterize both the nature and magnitude of the human risk in order to assist in making the decisions: political risk evaluations and risk management decisions.

Soundly based risk assessment, whether qualitative or, when possible, quantitative, assists in setting priorities and reaching decisions. We therefore support the efforts to improve the adequacy of scientific analysis in order to improve the basis and thus to make for sound social regulatory decisions which is the aim, we believe, or one of the aims, of H.R. 4192.

A lot has been said about models and I will make only a few short comments on them. Fundamentally, one of our concerns is the inappropriately heavy reliance on the output of models by regulatory agencies. I think it is quite clear that most models are merely generalized mathematical constructs which cannot be said to represent any specific case.

Thus, while they may give some indication of direction, they do not offer accurate estimates of risk at low doses. In a full risk assessment, one of the weakest parts may be the mathematical model; it is nonetheless a part, and, indeed, when looking at a full risk assessment, a full description of all uncertainties and the assumptions used is needed to assist in the weighing process as one looks at one part of an assessment versus another.

Peer review by independent science panels plays an important role in insuring the soundness and the completeness of the science base, and of the use of the science base, in agency risk analyses and we therefore welcome the reference to the study and the review of the role of science panels in H.R. 4192.

We also note that we would also like to support the National Research Council's frequently quoted report in which it discusses the roles of such panels and stresses that panel members should be selected solely on the basis of scientific expertise.

Over the past 10 to 15 years, Congress has increasingly directed that science play a key role in relating regulatory decisions to the character and magnitude of the risk. We believe that H.R. 4192 will make an important contribution to the improvement of the interface between the law and science. However, we would also like to stress that Congress must not slow down the progress already made to ensure the soundness and adequacy of the science base for regulatory decisions while awaiting the report contemplated by the bill.

Congress should continue to develop legislation that assures the adequacy of the science bases for regulating, including the use of panels of independent scientists to review and comment on agency risk analyses. We believe that promotion by Congress of science in regulatory proposal reduces disputes and litigation and in this way promotes speedier, more effective, and more feasibly implemented regulation when regulation is needed.

Thank you very much for hearing our views today.

[The prepared statement of Dr. Deisler follows:]

AIHC AMERICAN INDUSTRIAL HEALTH COUNCIL
1612 K STREET, N. W., SUITE 300, WASHINGTON, D.C. 20006 • (202) 659-0060

Statement Before The
Subcommittee on Natural Resources,
Agriculture Research and Environment
of the
Committee on Science and Technology
U.S. House of Representatives

on
H.R. 4192

By

Paul F. Deisler, Jr.

On Behalf Of
The American Industrial Health Council

June 5, 1984

NEW YORK OFFICE: 1075 CENTRAL PARK AVENUE, SCARSDALE, NY 10583 (914) 725-1492

Statement of Paul F. Deisler, Jr.

on

H.R. 4192.

Mr. Chairman and members of the Subcommittee. I am Paul F. Deisler, Jr. Vice President for Health, Safety and Environment of Shell Oil Company. I am also a member of the Board of Directors of the American Industrial Health Council ("AIHC") on whose behalf I am appearing today.

I welcome the opportunity to appear before the Subcommittee to present AIHC's views on H.R. 4192.

American Industrial Health Council

The American Industrial Health Council (AIHC) is an organization with nearly 100 corporate members and about the same number of participating trade associations. A current list of AIHC members is attached. As you can see, the members represent a broad industrial base ranging from producers of basic chemicals and metals to producers of drugs and consumer products.

AIHC does not act as a spokesman for any particular commodity. It was formed to mobilize the scientific and technical capabilities of the member companies to support proposals to strengthen the scientific basis for agency regulatory decisions. AIHC's focus has been on the role of science in the identification and control of chronic health hazards, particularly potential carcinogens.

The Role of Scientific Risk Assessment in Material Health Policy

AIHC believes that there is general agreement that a sound national health policy should identify and address all significant chronic health risks. Science and scientific risk assessment play a critical role in the achievement of that objective. AIHC, therefore, supports the intent of Title I of H.R. 4192 which is to provide demonstrations and to improve the methodology of scientific risk analysis and risk evaluation. Some information on risk assessment and its importance for the regulatory process may be useful to the Committee and place this bill in proper perspective.

Scientific Risk Analysis and Risk Evaluation

Using terms as defined in Title I of H.R. 4192, the regulatory process involves two basic functions:

- scientific risk analysis: the scientific process of objectively examining all available human and toxicity data for quality and relevance to the human situation in order to provide a scientific characterization of the potential human risk
- risk evaluation: the social/political function of deciding what regulatory action, if any, is appropriate. Social values - costs, feasibility, health benefits or other benefits are considered under the appropriate

statutory provisions in reaching that regulatory decision.

The scientific function is commonly called "risk assessment" rather than "risk analysis" and the regulatory function is usually called "risk management" rather than "risk evaluation". While we will use the terms as defined in the bill in this testimony, we concur with the recommendation of Dr. Joseph Rodricks that the definitions be revised to conform to those used in the recent NAS report on "Managing the Process: Risk Assessment in the Federal Government" (1983).

The scientific and regulatory functions are conceptually separate but interactive. Risk evaluation decisions are based on the scientific risk analysis, but risk evaluation is social/political and not scientific in nature.

The Role of Risk Analysis in the Regulatory Process

The great increase in research and testing in government, industry and academia in the past two decades has produced an abundance of data. These data indicate some kind of carcinogenic activity at some dose by some route of exposure in some test system for thousands of substances of many origins. The 100 or so short-term tests that are in various stages of development and validation have produced positive results on over 10,000 substances. These substances are by no means restricted to man-made chemicals. Natural substances (not additives) having potential carcinogenic activity are found throughout the food chain. Substances essential to life such as certain vitamins, minerals and hormones show carcinogenic potential in animal tests under certain conditions. The 10,000 substances found positive in the short term tests include, for example, oxygen.

The Need for Scientific Analysis

This spectacular and increasing amount of data varies in quality and in relevance to the human situation. It is critical to evaluate the data to characterize the magnitude and nature of the human risk in order to make difficult social/political risk evaluation or management decisions.

If regulatory decisions are not based on sound science, the regulations will be socially sound only by pure chance. Regulation without an adequate science base will result in wasted resources and, perhaps more important, a diversion in our attention from the more serious risks.

AIHC therefore supports efforts to improve the adequacy of scientific analysis in order to ensure sound social regulatory decisions. We support this objective of H.R. 4192.

What is the Content of a Scientific Analysis

Scientific risk analysis is the process of applying scientific criteria to determine the validity, quality and relevance of the data to the human situation. The examination includes but is not restricted to:

human data (epidemiology)

experimental data (bioassay studies and short-term tests)

exposure data (the actual human situation)

comparative metabolism (data to determine the relevance of animal data and route of exposure to the human situation).

Since the evidence varies in quality and relevance in each case, the scientific analysis must be case-by-case on a weight-of-the-evidence basis.

Statistical Models

There is an unfortunate public misunderstanding about the results obtained from mathematical models used in risk analysis. It derives from the inappropriate reliance on the output of the models by regulatory agencies. Models are simply generalized mathematical constructs which cannot be said to represent any specific case. They are often used in estimating risk at the low doses normally found in the human situation by statistically fitting the models to experimental data normally generated at much higher doses and then extrapolating to predict risks at low doses. At best, when the models are so used, they can offer general directional guidance but cannot give accurate estimates of risks at low doses.

Since models are statistical procedures, the models each generate their own most probable estimates of risk and, because of uncertainties in the data, one can also calculate confidence limits or error bands. We hear much about upper 95% confidence limits in connection with risk analysis.

Someone unfamiliar with statistics may assume a 95% confidence limit means 95% certainty the number is "right". It does not. In statistical terms, 95% confidence levels mean that one is 95% sure the number is below (perhaps way below) the upper confidence limit and above the lower confidence limit. The most probable number is somewhere between the confidence limits. Placing undue emphasis on the upper confidence level tends to over-estimate risk and to down-play the uncertainty in the risk analysis process. It also obscures the fundamental question of the correctness of the models used in the first place.

The statistical results do not characterize human risk scientifically. Models use only part of the data which should be examined in a full scientific analysis. The choice of models to use is complicated and involves many assumptions. All models contain inherently arbitrary assumptions; none have been biologically validated.

Scientific Analysis is Judgmental Not Statistical

This discussion of models is a prelude to the conclusion that results obtained using models are only one part of the data which should be examined in a scientific risk analysis. In fact they may be the weakest part. The scientific process is judgmental not statistical. Accordingly to make a comprehensive risk assessment the output of scientific models needs to be weighed with all other relevant data.

Importance of Independent Peer Review

Because the scientific process of risk analysis is judgmental, peer review by independent science panels plays an important role in ensuring the soundness of the science base in agency risk analyses. AIHC welcomes the reference to a review of the role of science panels in H.R. 4192. The recent NAS report on "Managing the Process: Risk Assessment in the Federal Government, National Academy of Sciences (1983) concludes that independent science panels play an important scientific role and are an important means of improving credibility of agency decisions. While the NAS report does not advocate the creation of a central panel of scientists to review risk analyses, it does recommend the referral of agency risk analyses to independent scientific panels for peer review before any major regulatory action is taken. (It also stresses that panel members should be selected solely on the basis of scientific expertise.)

The Interface of Law and Science

Over the past 10-15 years Congress has increasingly directed that science play a key role in relating regulatory decisions to the magnitude and character of the risk. AIHC believes that H.R. 4192 will make an important contribution to the improvement of the interface between law and science. However, Congress must not slow the progress already made to ensure the soundness and adequacy of the science base for regulatory decisions. While awaiting the report contemplated by H.R. 4192, Congress should continue to develop legislation that assures the adequacy of the science base for regulation and the use of panels of independent scientists to review and comment on agency risk analyses.

These steps to place reliance on sound science in the regulatory process will result in speedier and more effective regulation; there will be fewer false starts and attempts at regulation without a sound science base. Promotion by Congress of sound science in the regulatory process will reduce disputes and litigation and promote speedier, more effective and more feasibly implemented regulation when regulation is needed.

The end result will be greater health benefits and improved public credibility in regulatory decisions.

Title II

Title II of H.R. 4192 would have created a central science panel with very limited review functions. AIHC believes that a central science panel properly constituted could perform an important review function where the scientific issues were significant and involved two or more regulatory agencies. However, we understand Title II has been withdrawn by its sponsors and we will therefore not address the merits of the proposal further at this time.

AIHC MEMBER COMPANIES

AEtna Life Insurance Co.
Air Product & Chemicals, Inc.
Allied Corp.
American Cyanamid Co.
American Hoechst Corp.
AMOCO Chemical Corp.
Apollo Colors Inc.
Ashland Chemical Co.
  Div. of Ashland Oil, Inc.
Atlantic Richfield Co., The
Badische Corp.
Borg-Warner Chemicals,
  Div. Borg-Warner Corp.
Bristol-Myers
Buffalo Color Corp.
Burroughs Wellcome Co.
Celanese Corp.
Champion International
  Corporation
Chattem, Inc.
Chemplex Co.
Chesebrough-Pond's Inc.
Chevron U.S.A., Inc.
Ciba-Geigy Corp.
Columbia Nitrogen Corp.
Cordova Chemical Corp.
Cosden Oil & Chemical Co.
Coulton Chemical Corp.
Cyclo Chemicals Corp.
Dixie Chemical Co.
Dow Chemical U.S.A.
Dow Corning Corp.
Du Pont De Nemours
  & Co., Inc., E.I.
Eastman Kodak
Essex Chemical Corp.
Exxon Chemical Corp.
Firestone Tire & Rubber Co.
First Chemical Corp.
FMC Corp.
General Electric Co.
Goodyear Tire
  & Rubber Co.
Grace & Co., W.R.
Great Lakes Chemical
Heatbath Corp.

Hercules, Inc.
IBM Corporation
ICI Americas, Inc.
ITT Rayonier Inc.
Kay-Fries, Inc.
Kenrich Petrochemicals, Inc.
Loctite Corp.
Lord Corp.
Merck & Co., Inc.
Merichem Co.
Mobay Chemical Corp.
Mobil Research & Development Corp.
Monsanto Co.
Mooney Chemicals, Inc.
Morton Chemical
NALCO Chemical co.
National Distillers
  & Chemical Corp.
Olin Corp.
Owens-Corning
  Fiberglass Corporation
Pennwalt Corp.
Pfister Chemical Corp.
Pfizer, Inc.
Phillips Chemical Co.
Pope Chemical Corp.
PPG Industries, Inc.
PVS Chemicals, Inc.
Procter & Gamble Co., The
Rohm & Haas Co.
Ruetgers-Nease
  Chemical Co., Inc.
Shell Oil Co.
Standard Oil Co. (Ohio)
Stauffer Chemical Co.
Street & Co., Inc., R.R.
Sun Chemical Corp.
SunOlin Chemical Co.
3M Co.
Uhlich & Co., Inc., Paul
Union Carbide Corp.
Univar Corpration
Velsicol Chemical Corp.
Vulcan Materials Co.
Witco Chemical Corp.
Xerox Corp.

ASSOCIATION MEMBERS

Adhesives and Sealants Council
Adhesives Manufacturers Assn.
Aluminum Assn., Inc.
American Boiler Manufacturers Assn.
American Chemical Institute
American Coke and Coal Chemicals Institute
American Foundryman's Society
American Iron and Steel Institute
American Meat Institute
American Mining Congress
American Paper Institute
American Textile Manufacturers Institute
American Welding Society
American Wood Preservers Institute
Asbestos Information Assn.
Associated General Contractors
Associated Industries of Massachusetts
Battery Council, Inc.
Business Roundtable
California Fabricare Institute
Canadian Pulp and Paper Assn.
The Carpet and Rug Institute
Chamber of Commerce of the U.S.
Chemical Manufacturers Associaton
Chemical Specialties Management Council
Chemical Specialties Manufacturers Assn.
Chlorine Institute, Inc.
Cosmetic, Toiletry and Fragrance Assn., Inc.
DETO/US Operating Committee of ETAD
Diesel Automobile Associaton
Distilled Spirits Council of the U.S.
The Dry Cleaners Exchange
Dry Color Manufacturers Assn.
Foundry Supply Manufacturers Group
Graphic Arts Technical Foundation
Gypsum Assn.
Hardwood Plywood Manufactures Assn.
Health Industry Manufacturers Assn.
Independent Petroleum Assn.
Institute of Industrial Launderers
International Fabricare Institute
International Institute of Synthetic Rubber Producers, Inc.
Man-Made Fiber Producers Assn.
Motor Vehicle Manufacturers Assn. of the U.S.

National Agricultural Chemicals Assn.
National Assn. of Manufacturers
National Assn. of Printing Ink Manufacturers
National Assn. of Water Companies
National Constructors Assn.
National Cotton Council
National Electrical Manufacturers Assn.
National Federation of Independent Business
National Forest Products Assn.
National Lime Assn.
National Paint and Coatings Assn.
National Particleboard Assn.
National Pest Control Assn.
National Petroleum Refiners Assn.
Neighborhood Cleaners Assn.
New Jersey Business and Industry Assn.
Nickel Producers Environmental Research Assn.
Ohio Cleaners
Organization Resources Counselors, Inc.
Pharmaceutical Manufacturers Assn.
Polyurethane Manufacturers Assn.
Portable Sanitation Assn.
Printing Industries of America, Inc.
Proprietary Assn.
The Refractories Institute
Rubber Manufacturers Assn.
Safety Management Assn.
Scientific Apparatus Makers Assn.
Single Service Institute
The Soap and Detergent Assn.
The Society of the Plastics Industry, Inc.
Steel Plate Fabricators Assn. Inc.
Synthetic Organic Chemicals Manufacturers Assn., Inc.
Synthetic Rubber Manufacturers Assn.
Textile Rental Services Assn. of America
Thermal Insulation Manufacturers Assn.
Truck Trailer Manufacturers Assn.
The Tobacco Institute
Underwood Jordan Associates
Virginia Assn. of Launderers and Cleaners, Inc.
Western Wood Products Assn.
Wisconsin Fabricare Institute, Inc.

P. F. DEISLER, JR.

VICE PRESIDENT - HEALTH, SAFETY & ENVIRONMENT
SHELL OIL COMPANY

Paul Deisler joined Shell Development Company as an Engineer in Emeryville, California, in 1952. His educational background includes a B.S. degree in Chemical Engineering from Texas A&M, and M.S. and Ph.D. degrees from Princeton University in the same field.

In 1963, he was assigned to Shell Chemical Company as Manager, Process Development Department, Industrial Chemicals Division. He subsequently became Manager, Martinez Plant, General Manager, Ammonia Division; and Manager Chemical Economics Department.

In 1969, he was elected Vice President Transportation and Supplies. In 1971, he accepted an assignment with Compania Shell de Venezuela as Director of Supply and Refining and returned to the United States as a Vice President of Shell Chemical Company in mid-1973, and, in mid-1974, became Vice President Research and Engineering-Products. He assumed his present position in September 1976.

Mrs. SCHNEIDER. Thank you very kindly.

Dr. Mallino, would you like to carry on, please.

Dr. MALLINO. Thank you very much, Madam Chairwoman. I would like to note that the Industrial Union Department of AFL-CIO represents 53 international unions in a number of different industries from steel, autos, glass, and textile.

With me today is Sheldon Samuels who is director of our department health, safety and environment and who was also the chairman of the National Cancer Advisory Board's Subcommittee on Environmental Carcinogens.

The Industrial Union Department opposes H.R. 4192 for five specific reasons: First, the bill fails to recognize that risk assessment is little more than a very limited analytical tool which produces numbers that are merely suggestive. It is based on highly theoretical mathematical models and subject to a host of assumptions and variables. Its limitations are such that it ought not be used as determining criteria for making regulatory decisions affecting public safety and health. Neither should it be imposed as a generic analytical requirement qualifying the regulatory criteria established in substantive law.

Second, the related idea of using risk assessments as the basis for "risk evaluations" and defining "acceptable levels of risk" is a form of pseudoscience that seeks to mask political and policy decisions. In this respect, neither risk assessment nor risk evaluation are magic substitutes for informed scientific and public policy judgments.

Third, turning the policy management of risk assessment over to OMB or some other White House agency would politicize this limited analytical tool and turn it into a policy instrument. The development and use of risk assessment should be left in the hands of those who know and understand its limitations rather than those who might seek political or policy advantage.

Fourth, the risk assessment and risk evaluations called for in this bill bring into play cost/benefit analysis, which is another so-called objective scientific tool that is also loaded with political and policy implications. No matter how pure the risk assessment analysis, ultimately the policy question comes down to "how much will it cost" to achieve a particular level of risk and "is it worth it?" We think that these broad social and political questions ought to be left to the Congress and the statutes it writes and not to the supposed "science" of cost/benefit analysis and risk assessment.

Finally, H.R. 4192 is simply unnecessary. The various regulatory agencies are already doing risk assessments and have been for some time. According to Margaret Heckler, Secretary of Health and Human Services in a letter to OMB's David Stockman:

> In summary, although we endorse most of the bill's objectives, we believe the bill is unnecessary. This Department in cooperation with the Environmental Protection Agency, the Department of Labor and the Consumer Product Safety Commission is currently participating in the development of an Interagency Risk Management Council to address the major objectives of the bill.

Mr. Chairman, the labor movement very rarely agrees with this administration, but in this instance we think Secretary Heckler is at least on target. Unless the real purpose of this bill is to further promote the antiregulatory political agenda under the guise of "risk assessment," then most of what it seeks to accomplish is already being done and there is no need to clutter up the Federal statute books.

More importantly, given the scientific limitations of risk assessment and the rather dubious nature of risk evaluation, we believe that the Congress ought not legitimize through statute something that at best is merely an analytical tool.

What I would like to do for the record—I haven't given to these staff—is introduce for the record three sets of documents: First, Secretary Heckler's letter; second, a letter from Dr. Gilbert Oman from the Universty of Wahington's School of Public Health on risk assessment; and third, two reports by the National Council Advisory Board on Risk Assessment in using risk assessment for determination of carcinogenes. Thank you.

[The referenced documents appear in the Appendix.]

[The prepared statement of Dr. Mallino follows:]

Statement of the Industrial Union Department, AFL-CIO

By David L. Mallino, Ph.D., Legislative Representative

On H.R. 4192

Risk Assessment Research and Demonstration Act of 1983

Before the Subcommittee on Natural Resources,
Agriculture Research and Environment

Of the Committee on Science and Technology

U.S. House of Representatives

June 5, 1984

Industrial Union Department, AFL-CIO
815 Sixteenth Street, N.W., Washington, D.C. 20006
202/842-7800
Howard D. Samuel, *President*
Elmer Chatak, *Secretary-Treasurer*

PRINTED IN U.S.A.

About IUD

The Industrial Union Department is the largest of the AFL-CIO's constitutional departments, with 57 affiliated unions representing 5½ million members.

As a constitutional department, IUD is a semi-autonomous branch of the AFL-CIO. The department is financed directly by per capita payments from its affiliates. It is directed by a president and a secretary-treasurer who are elected at biennial conventions. The governing body is an executive council composed of the two officers and 24 members, who are principal officers of affiliated unions.

History

The IUD stems from the 1955 merger agreement between the AFL and the CIO, which provided for a new industrial union department within the merged federation. Walter Reuther, then CIO and UAW president, was elected its first president.

Reuther was succeeded in 1968 by I.W. Abel, president of the United Steelworkers of America, who served until 1977. Jacob Clayman succeeded Abel for one term, until 1979, when Howard D. Samuel was elected president and Elmer Chatak, secretary-treasurer. Clayman had served as IUD secretary-treasurer from 1975 to 1977. James Carey, former IUE president and CIO secretarial treasurer, was the department's first secretary-treasurer, in office from 1955 to 1965.

Function

From its inception, the function of IUD has been to provide support services to affiliated unions in those areas where they share common concerns and where special efforts are needed to supplement the work of individual unions and the AFL-CIO.

IUD has a tradition of working with coalitions to strengthen labor's position on key issues. The department helped create the OSHA/Environmental Network, the Full Employment Action Council, the Consumer Federation of America, and a number of others.

Programs

Organizing – More than one-third of IUD's resources are devoted to organizing. The department initiated the concept of cooperative organizing under then President Reuther in 1963, and has provided major support for many organizing campaigns since then. Under this approach, unions assign their organizers to work under the direction of an IUD coordinator. The method encourages cooperation among affiliates through the pooling of available resources and virtually eliminates jurisdictional disputes. The organizing section is located in Atlanta, Ga., with field offices in the Mid-South and Southeast.

Coordinated Bargaining – Another hallmark of IUD is coordinated bargaining, which brings together different unions having contracts with the same company to give them stronger leverage at the bargaining table. More than 40 unions participate in 71 different company committees, involving about 2,200 bargaining units and three-quarters of a million workers.

Safety, Health & Environment – Ever since it played a leading role in passage of the 1970 Occupational Safety and Health Act, IUD has taken the initiative in the courts and in legislative battles to assure proper implementation of the law. Through its work with the OSHA/Environmental Network, the department also has helped defend environmental protections.

Economic Policy – IUD has responded to downturns in the economy by examining and calling attention to the long-term problems faced by America's industrial sector. The department is a prime mover in efforts to develop a national industrial policy for the U.S. that will revitalize the industrial sector.

International Trade – This area has been an important concern to IUD because of the enormous impact that the policies of foreign governments have on U.S. industries and industrial union members. IUD continues to develop analyses, educational efforts and legislative approaches to key areas of trade policy, often through coalition activities.

Pensions – IUD monitors regulatory and legislative activities that could affect the status of benefit plans negotiated by its affiliates. The investment policies of private pension plans are an area of special concern for the department, which publishes *Labor & Investments*, the principal publication in this field.

Howard D. Samuel
President

Howard D. Samuel's career in the labor movement has spanned more than 30 years, and culminated in his election as president of the IUD in September 1979. For most of the period 1949-77, he was associated with the Amalgamated Clothing Workers of America, first as an organizer, then assistant president and from 1966 as an international vice president. He directed the union's political and legislative activities and as head of its union label department coordinated the union's boycott campaigns.

From January 1977 until his election as IUD president, Samuel was deputy under secretary of labor, directing the U.S. Labor Department's International Labor Affairs Bureau.

Samuel has been active in politics, serving as a delegate to state and national Democratic conventions, and has served on several government commissions and on the boards of numerous community organizations. A graduate of Dartmouth College, he also co-authored two books on government.

Elmer Chatak
Secretary-Treasurer

Elected IUD secretary-treasurer in September 1979, Elmer Chatak is responsible for administering the financial affairs of the department as well as providing direction to its organizing and coordinated bargaining activities. Since 1951, he has been involved in union organizing campaigns, first on the CIO staff for five years, then with the United Steelworkers.

The USWA loaned Chatak to IUD in 1963 to serve as organizing coordinator for the Mid-Atlantic cooperative organizing campaign, directing a staff of 35 organizers from 20 unions. His win record of 153 of 197 campaigns covered 31,500 new members.

In 1968, Chatak returned to USWA to establish an organizing department and serve as the first director, a post he held until being elected IUD secretary-treasurer. During that period, about 3,000 bargaining units with over 250,000 workers were organized into the union.

Chatak was born on December 15, 1929, in Acmetonia, Pennsylvania.

Mr. Chairman, Members of the Subcommittee. My name is David Mallino and I am the Legislative Representative of the Industrial Union Department of the AFL-CIO.

The Industrial Union Department represents 53 international unions engaged in such industries as steel, autos, rubber, chemicals, printing, food processing, textile and clothing, aerospace and manufacturing of all types.

For some years now, we have been concerned with political and corporate efforts to substantially weaken the federal regulatory system, particularly those parts of the system designed to protect occupational, environmental, and consumer safety and health. Initially, the anti-regulatory campaign was aimed at the substantive statutes themselves like the Occupational Safety and Health Act, the Clean Air Act and the Consumer Product Safety Act. To its credit, the Congress resisted most of these attacks and largely preserved the integrity of the basic regulatory laws.

More recently, however, the anti-regulatory effort has shifted to a more generic campaign cloaked in the mantle of so-called "regulatory reform," which is little more than a back-door approach aimed at weakening all the regulatory statutes at the same time. Although initially harmless in appearance, the combined impact of the regulatory reform proposals would be to effectively shutdown the regulatory process. The procedural aspects alone would impose burdens on the regulatory agencies that would stop effective regulation and transform these agencies into mere study and analysis centers.

Among the more prominent regulatory reform proposals have been those to impose generic requirements for cost/benefit and risk assessment analysis. The claim of those supporting the legislative imposition of these analytical exercises is that regulatory agencies should be required to apply "scientific" and "objective" criteria to regulatory decision making.

Without getting into a big technical argument, neither cost/benefit nor risk assessment analyses are as "scientific" or "objective" as they might first appear. Indeed, like any tool they can and have been misused or misapplied. They can and have been promoted for purely political and policy purposes as a mask for weakening or at least slowing down the regulatory process.

Having said all this, the question is how H.R. 4192 fits into this overall regulatory reform scheme. On the face of it, the bill is unnecessary, since most of what it calls for is already being done in the federal government. On the other hand, however, it may also represent yet another effort to retard effective federal safety and health regulation.

As such, we oppose the bill for five specific reasons.

[First, the bill fails to recognize that risk assessment is little more than a very limited analytical tool which produces numbers that are merely suggestive. It is based on highly theoretical mathematical models and subject to a host of assumptions and variables. Its limitations are such that it ought not be used as a determining criteria for making regulatory decisions affecting public safety and health. Neither should it be imposed as a generic analytical requirement qualifying the regulatory criteria established in substantive law.

Second, the related idea of using risk assessments as the basis for "risk evaluations" and defining "acceptable levels of risk" is a form of pseudo-science that seeks to mask political and policy decisions. In this respect, neither risk assessment nor risk evaluation are magic substitutes for informed scientific and public policy judgements.

Third, turning the policy management of risk assessment over to OMB or some other White House agency would politicize this limited analytical tool and turn it into a policy instrument. The development and use of risk assessment should be left in the hands of those who know and understand its limitations rather than those who might seek political or policy advantage.

Fourth, the risk assessment and risk evaluations called for in this bill bring into play cost/benefit analysis, which is another so-called objective scientific tool that is also loaded with political and policy implications. No matter how pure the risk asessment analysis, ultimately the policy question comes down to "how much will it cost" to achieve a particular level of risk and "is it worth it?" We think that these broad social and political questions ought to be left to the Congress and the statutes it writes and not to the supposed "science" of cost/benefit analysis and risk assessment.

Finally, H.R. 4192 is simply unnecessary. The various regulatory agencies are already doing risk assessments and have been for some time. According to Margaret Heckler -- Secretary of Health and Human Services (HHS) -- in a letter to OMB's David Stockman:

> "In summary, although we endorse most of the bill's objectives, we believe the bill is unnecessary. This Department in cooperation with the Environmental Protection Agency, the Department of Labor and the Consumer Product Safety Commission is currently participating in the development of an Interagency Risk Management Council to address the major objectives of the bill."

Mr. Chairman, the labor movement very rarely agrees with this Administration, but in this instance we think Secretary Heckler is at least on target. Unless the real purpose of this bill is to further promote the anti-regulatory political agenda under the guise of "risk assessment," then most of what it seeks to accomplish is already being done and there is no need to clutter up the federal statute books. More importantly, given the scientific limitations of risk assessment and the rather dubious nature of risk evaluation, we believe that the Congress ought not legitimize through statute something that at best is merely an analytical ~~instrument~~ tool.]

Mrs. SCHNEIDER. Thank you.

Now, Mr. Sheehan.

Mr. SHEEHAN. Thank you, Madam Chairman. My name is Jack Sheehan, legislative representative for the Steel Workers Union. The bill before you is a risk management bill. Admittedly these terms "risk management," and "risk assessment," are somewhat interrelated and I find that when we were reading the literature in this area the definitions were somewhat difficult and I must admit rather various.

There is no precision apparently in this area as to the definitions and I might indicate on the side it is highly risky to legislate at least at the conceptual level. However, according to the act, risk assessment has two component parts: risk analysis, which is an objective component and risk evaluation.

Now, the bill is being advanced as an objective scientific tool. However, the subjective aspect of rulemaking remains intact because section 104 identifies that risk evaluation is an essential part of the system. That exercise requires, and I quote: "Judging the acceptability of various levels of risk to individuals, society and the environment."

Our basic concern applies to this judgmental characteristic which "concentrates on decisions defining acceptable levels of risk, Section 102(e)." Even more so directed is our concern that the proposed bill recommends that a regulatory agency should consider "alternative courses of action and may therefore involve competitive risk assessments, Section 102(f)."

Now, Madam Chairman, there are quite a number of such concepts that are displayed within this bill that make highly risky the effort to move into legislating in the field of risk management. The bill is unnecessary because most of what it accomplishes in the way of risk assessment, research, and coordination is already being done within the Federal Government.

While we do not necessarily agree with everything the regulatory agencies are doing, on the face of it, it appears that much of what is called for in the bill is already being done administratively without legislative mandate. If, on the other and, the real purpose of the bill is to take up where the cost benefit advocates leave off, then the bill should be rejected as dangerous to the environment and public health.

Indeed like cost benefit analysis, risk assessment is being promoted as some kind of an objective, scientific tool which can lead to more reasonable regulation and, therefore, should be used to make regulatory decisions.

What we are not often told is that the tool itself is a very primitive instrument which yields very uncertain results.

One of the major problems with this bill is that it does not distinguish between qualitative- and quantitative-risk analysis. Qualitative-risk analysis is simply a process of determining whether or not a particular activity or agent is hazardous to human health. Such determinations are made on the basis of epidemiological, clinical, toxicological, and animal studies. This qualitative work is both proper and necessary and, in fact, should be expanded because far too little is known about the thousands of potentially hazardous chemicals in use today.

Quantitative-risk analysis, on the other hand, is the process by which the risk of disease or death in a population exposed to a particular toxic agent is related numerically to the pattern of exposure. In other words, what this analysis seeks is to determine how many people in a given exposed population will become diseased or die at various levels of exposure. The exercise is dependent upon theoretical, mathematical modeling, data monitoring, and laboratory work.

And again the point here is that it is a highly uncertain exercise that we would be engaged in.

[The prepared statement of Mr. Sheehan follows:]

TESTIMONY

JOHN J. SHEEHAN, LEGISLATIVE DIRECTOR

UNITED STEELWORKERS OF AMERICA

before the

SUBCOMMITTEE ON NATURAL RESOURCES, AGRICULTURE
RESEARCH AND ENVIRONMENT
COMMITTEE ON SCIENCE AND TECHNOLOGY

on

RISK ASSESSMENT IN THE FEDERAL GOVERNMENT

June 5, 1984

Washington, D.C.

Mr. Chairman, Members of the Subcommittee. My name is John J. Sheehan, and I am the Legislative Director of the United Steelworkers of America.

At the outset let me state that our union is opposed to H.R. 4192 "The Risk Assessment Research and Demonstration Act of 1983." At best, the bill is unnecessary, and at worst, it is yet another back door attack on the federal safety and health regulatory system.

The bill is unnecessary because most of what it seeks to accomplish in the way of risk assessment research and coordination is already being done within the federal government. Those agencies primarily responsible for occupational, environmental, and consumer safety and health have not only been involved in the development of risk assessment as an analytical tool, but are now engaged in an interagency coordinating program through the recently created Interagency Risk Management Council. While we do not necessarily agree with everything the regulatory agencies are doing, on the face of it, it appears that much of what is called for in H.R. 4912 is already being done administratively without legislative mandate.

If, on the other hand, the real purpose of the bill is to take up where the cost/benefit advocates leave off, then the bill should be rejected as dangerous to environmental and public health.

Indeed, like cost/benefit analysis, risk assessment is being promoted by some as an objective, scientific tool which can lead to more "reasonable" regulation and, therefore, should be used to make regulatory decisions. What we are not often told is that the tool itself is a very primative instrument which yields very uncertain results. We know of no scientist familiar with risk assessment techniques who has not qualified its use, application and results. Moreover, the numbers which flow from risk assessment are largely dependent upon the initial assumptions on which the entire exercise is premised: assumptions which often are not always value-free.

One of the major problems with this bill is that it does not distinguish between qualitative and quantitative risk analysis.

Qualitative risk analysis is simply the process of determining whether or not a particular activity or agent is hazardous to human health. Such determinations are made on the bases of epidemiological, clinical, toxicological, and animal studies. This qualitative work is both proper and necessary and, in fact, should be expanded because far too little is known about the thousands of potentially hazardous chemicals in use today.

Quantitative risk analysis, on the other hand, is the process by which the risk of disease or death in a population exposed to a particular toxic agent is related numerically to the pattern of exposure. In other words, what this analysis seeks is to determine how many people in a given exposed population will become diseased or die at various levels of exposure. The exercise is dependent upon theoretical, mathematical modeling, data monitoring, and laboratory work for determining the behavior of chemicals in the environment. It is a highly complex activity subject to a number of important variables, including various routes of exposure, different chemical concentrations, various human and life-style activities, differences in biological conversions, chemical reactions and environmental transport mechanisms. Thus, quantitative risk analysis is, at the very best, an uncertain science which can produce uncertain, or, at least, highly qualified, results.

To add to the uncertainties by introducing even more uncertain concepts such as "risk evaluation, acceptable levels of risk and comparative risk assessment" — as H.R. 4192 does — is to move the whole risk assessment debate into the world of politics and policy making. To base all these additional notions on what is widely agreed to be a primitive statistical science is to misuse the tool itself. Like cost/benefit analysis, this purely analytical tool is being politicized for purposes other than those for which it was designed. In effect, the tool is being taken out of the hands of the scientists, who understand its limitations, and placed in the hands of the politicians and policy makers who often have something other than science in mind. Indeed, we are afraid that although this bill only calls for "a demonstration" project, that in the wrong hands, risk assessment, risk evaluation, comparative risk analysis and acceptable levels of risk all become political code words for a license to weaken or destroy the socially protective regulatory system.

Thus, Mr. Chairman, we do not believe that the Congress ought to be legislating in an area which is better left to the scientists and medical professionals. Risk assessment is merely a tool and has no magic powers to solve social and political problems. We should let it remain in the tool chest to be used for the limited purposes for which it is intended. We should not dignify it by an Act of Congress.

Mrs. SCHNEIDER. Are we not already involved in a highly unpredictable arrangement?

Mr. SHEEHAN. Well, I think, Madam Chairman, there are two parts that would come to my mind in answering that question. One, the scientific aspect that this bill begins to build upon; namely, the so-called risk analysis. Obviously all of us who promote regulatory intervention would like to get as much scientific analysis out on the table.

Our objection to this bill is that it takes the so-called best we can get, the best available scientific knowledge and then builds into it the risk evaluation. That admittedly, I might say, is maybe an uncertain area but those are the social conditions that we seek congressional intervention.

We pass laws up here that make legislative judgment about the social conditions and do indicate, yes, the administration regulation in that area. I am afraid that the proponents of this bill would somehow or the other infer that that later aspect, namely risk evaluation, is either subject to some kind of objective definition and squeezes out the uncertainty.

I am trying to indicate here that it does not do that.

Mr. RITTER. I understand Mr. Sheehan's concern with the risk evaluation side being somehow an element of the bill which we are attempting to mathematize or formalize. We are not, as a matter of fact, in reading from section 20(e), that is simply a statement of findings and declarations, which only attempt to lay out the kind of intellectual universe and in no way, shape, or form involve a formal activity operational segment of the bill.

We are defining terms here. A study of risk assessment talking about risk assessment is basically a multistep process consisting first of a scientifically based risk analysis which concentrates on risk probability and conditions of risk followed by a risk evaluation which is more judgmental in nature and concentrate on decisions defining acceptable levels of risk.

I don't think there is anybody in the world who would argue with that. And what I am saying is here we are dealing with a risk assessment and Congress, the public, the various competing interest groups, will eventually get to risk evaluation, but in no way, shape, or form does this bill do that.

Mr. SHEEHAN. If I could make a quick comment also that finding that is up here in the front part of the bill, although I wouldn't——

Mr. RITTER. Setting out the definitional?

Mr. SHEEHAN. I wouldn't discount findings too easily because the Supreme Court's rulings subsequently on findings themselves have unseated certain intentions of the legislation, but also you will find in section 104(c) of the act the same emphasis upon "judging the acceptability of various levels of risk" under the terminology of risk evaluation. And I guess the one point I would focus on here is that the advocates of the bill should or the other seem to promote the idea that this is simply a scientific endeavor, looking for, obviously, something we always want is a certitude. But determining the acceptable levels of risk, not certitude, it is a social judgment——

Mr. RITTER. If the gentleman would yield.

Again, even in 104(c), what we try to do is simply make definitions as to what these different phases are. We don't get involved in the process of risk evaluation, but in order to understand assessment, in order to understand analysis, you have to set down the framework where it fits and we again—I will quote from 104(c)—it simply says the term risk evaluation means the process of judging the acceptability of various levels of risk to individuals, society and the environment, and we do risk evaluations politically, socially, economically all the time. This bill does not.

Mr. SHEEHAN. Could I go one step further on that?

So the bill does have a very good consistency in it. It seems to me, by the way——

Mr. RITTER. It tries to define the world in which we are dealing with here in the risk assessments.

Mr. SHEEHAN. And it moves forward into section 108 in which the cooperating agency, or whatever is to be the new coordinator here, will recommend legislation.

So we are moving from step to step, moving into this whole area of what you might say is just a conceptual issue. Now you are going to statutory risk put into legislation what is an acceptable level of risk——

Mr. RITTER. No, that is not the——

Mr. SHEEHAN. It is a legislative decision and——

Mr. RITTER. I agree.

Mr. SHEEHAN [continuing]. And legislative efforts on the Hill to promote the various regulatory interventions, that issue is constantly faced by the Congress and a level of judgment is made by way of——

Mrs. SCHNEIDER. I would like to reclaim my time because I see that we are somewhat going back and forth on this same issue.

Whether you two gentlemen would ever agree on that particular point remains to be seen and maybe you can get out in the halls.

Mr. RITTER. Could I make one last comment on 108, since we have covered 102, 104?

Mrs. SCHNEIDER. One miniscule comment.

Mr. RITTER. It says recommendations for legislation needed to implement and facilitate the use of risk assessment within federal agencies, it in no way implies legislation based on risk evaluation. It never does. The bill doesn't really function on evaluation. It simply defines that as part of the universe here.

Mrs. SCHNEIDER. Mr. Mallino, I would like to ask a question.

One of your objections that you state in your testimony is that the idea of using risk assessments as a basis for risk evaluations and defining acceptable levels of risk, do you think that there is such a thing as an acceptable level of risk?

Dr. MALLINO. There probably are acceptable levels of risk. We, however, would object to—we think if there are acceptable levels of risk then those acceptable levels of risk ought to be debated and written into the statute, the regulatory statutes.

The occupational safety and health act make certain judgments, the Congress made those judgments and based upon those judgments it said that the regulatory agency shall do thus and so.

If we are going to debate the acceptable levels of risk, then we ought to debate them when we are writing those judgments into the statutes.

We ought not to pretend, however, that science—this is where we are getting into the argument that Jack and Congressman Ritter just left off—we ought not to pretend that science is some sort of a magic substitute to define those acceptable levels of risk.

Those are social and political questions that we think ought to be addressed in the social and political arena and we ought not to mask those decisions under the rubric of science.

Mrs. SCHNEIDER. Let me ask one of the social questions. That is a question of cost. To what degree should costs be a consideration in deciding when a particular risk should be reduced?

Dr. MALLINO. Again, you have to look at each one of the statutes. The occupational safety and health act never mentions cost. As a matter of fact, when cost was debated during the process of enacting the bill, the term cost or economics was purposely not put into the act.

The way the Supreme Court has interpreted that particular act is that, while economics is a factor, it is not the only factor.

What I am trying to get at here is that each time we pass a regulatory statute dealing with a particular area, particularly social concern, those questions are addressed.

Everybody has a chance to participate in the debate and the Congress makes a particular judgment.

What we are trying to do here, unfortunately, and what the movement with respect to cost/benefit analysis is to pass some sort of a generic tool and make that applicable to all of the regulatory statutes.

We think that is a mistake.

Mrs. SCHNEIDER. Well, Mr. Deisler, I would like to ask you, if you support this legislation, then there must be something in your own experience as being the representative of the American Industrial Health Council and being responsible for health safety and the environment, three intricate areas, what are the Federal agencies not doing now that they should be doing in terms of risk assessment?

Dr. DEISLER. The Federal agencies are doing a substantial amount of risk assessment. As we heard from some of the people in the first panel this morning, they are doing rather different things in many cases.

There is sometimes a substantial inconsistency between them. The virtue, we think, of this particular bill is that it basically is a research bill, proposing to examine the different aspects of risk assessment through the demonstration projects, and perhaps to bring some broader understanding and better consistency where this is possible between agencies.

I don't know if I have answered your question completely, but that is an answer.

Mrs. SCHNEIDER. Congressman Ritter wanted to raise a question?

Mr. RITTER. I have a feeling that Mr. Mallino and Mr. Sheehan have combined the assessment and the management phases together and don't differentiate.

The first recommendation of the National Academy of Sciences was that we should make the attempt to separate out assessment from management, and that is really what the bill attempts to do.

Dr. **Mallino**. The way I read the definition part of this bill is that the definition of risk assessment now includes risk evaluation, defining acceptable levels of risk—

Mr. **Ritter**. No, it does not. It simply defines. I went through—

Dr. **Mallino**. I know, Congressman Ritter—any of us who deal with legislation know—if you let me define the terms, then you can have the rest of the bill, and the way that bill will come out is the way I define the words and here we started off talking about risk assessment and the definition of risk assessment seems to me that the scientists who deal with risk assessment will come in and have given a very narrow scientific definition of what risk assessment analysis is.

The bill expands that definition to include——

Mr. **Ritter**. It does not. It does not. It expressly separates out the definitions of assessment and evaluation to make sure that it is understood.

We could always, if this would win the support of the AFL-CIO Industrial Union Department, simply excise these definitions because, believe me, they don't add that much to the bill. They are simply laying out context.

Dr. **Mallino**. Then you would have to define, come up with an acceptable scientific definition of risk analysis. Frankly, Congressman Ritter, the two things that have in effect set us off is what we perceive to be a political expansion of the term to include risk evaluation, acceptability, defining, judging acceptability or various levels of risk and this whole business of comparative——

Mr. **Ritter**. You can't find one place in the bill that does that. It simply defines risk evaluation.

Dr. **Mallino**. The terms——

Mr. **Scheuer**. Excuse me. On page 6 of the bill, in the definitions, item (d), section 104(d) states, the term risk assessment in quotation marks, assessment of risk in quotation marks means the total process including both risk analysis and risk evaluation. That is a perfectly simple statement of what risk assessment means.

Dr. **Ahmed**. May I make a comment?

Mr. **Ritter**. Our bill is designed to deal with the risk analysis. There are some definitional problems that have emerged since the publication of this report and the terms are changing, but we are not dealing and at no place in the operational phase of the bill do we attempt to go into the area of risk evaluation.

Dr. **Ahmed**. Mr. Chairman, could I make a statement on that?

Mr. **Scheuer**. Very briefly.

Dr. **Ahmed**. I just want to point out that risk assessment, as defined by your bill, does include both technical and policy questions as defined under (d) here, and I think it is important for you to realize another point, Congressman Ritter, none of the Academy reports ever said there could be a clean break between risk assessment and evaluation.

There has to be a process between the two depending upon the different statutory requirements the agencies perform. So it seems to me regardless of how you clean up the definition here, to make a claim that this particular process can be completely separated is not something that—you can read comments out of reports out of context and it may give you the impression that these things should be separated, but in the total context no report, including the earlier Academy report, ever suggested that in practice this kind of process can ever occur without both considerations occurring at the same time.

Mr. **Ritter**. It is a question of emphasis.

Mr. **Scheuer**. Mr. Sheehan.

Mr. **Sheehan**. Mr. Chairman, I was just going to pick up on the comments that Congressman Ritter made and maybe a recommendation that he was forwarding is that he would be willing to strike from the bill all references to the word risk assessment and risk evaluation and I think that might be worth looking at.

Mr. **Ritter**. We could use the National Academy definition of assessment which is essentially analysis and it gets rid of the evaluation side.

I think that is a reasonable suggestion.

Mr. **Deisler**. I would like to comment that I think that last suggestion would be a very good one since that particular committee, in that study, did examine with great care and with a wide variety of knowledgeable representatives—this very issue.

Mr. **Scheuer**. OK.

Ms. **Dubrowski**. May I make one brief concluding comment? Much of the debate here has focused on the controversy around risk management and risk evaluation. There is another point which should not be lost; that even risk assessment, narrowly defined, the use of it is controversial and to the extent this bill emphasizes comparative risk assessment and the use of risk assessment, not just for priority setting, but for decisionmaking, there is still concern about that point.

Mr. **Samuels**. A three sentence comment, if I may, Mr. Chairman. My observation of listening to the dialog this morning is that the Congress is involved in a nominalistic dialog which may not be worth their time.

Mr. **Scheuer**. Would you explain what a nominalistic dialog is?

Mr. **Samuel**. We are just playing with definitions.

Let me give you an example.

Mr. Deisler, Dr. Deisler, in talking about mathematical models, could have referred to an important observation of every scientist, including himself, involved in the 1-year study of quantitative risk assessments by the National Cancer Advisory Board. That is, that the models are currently untestable and unverifiable. The fact is that they are chosen for use by the agencies, by making subjective value judgments. For that reason we endorse Dr. Ahmed's conclusion that setting priorities alone at this time can be served by quantitative risk assessments in the regulatory arena.

Mr. **Scheuer**. Thank you, very much. It has been a very interesting panel and we appreciate your contribution and your patience.

STATEMENTS OF DR. RICHARD WILSON, CHAIRMAN, DEPARTMENT OF PHYSICS, HARVARD UNIVERSITY, AND DAVID SIVE, ESQ., WINER, NEUBURGER & SIVE

Dr. WILSON. It is an honor and privilege to be asked to talk to you today about the proposed bill, H.R. 4192.

In this testimony, I want to summarize how an improper attention to the problem of uncertainty has caused many of the misuses of risk assessment and many of the misstatements by the opposers of risk assessment.

Risk implies uncertainty and when it is uncertain whether a chronic health hazard exists, there is a risk that it does. A risk of a risk—and therefore a risk to health. All too often, this risk of the unknown is ignored.

I illustrate by a caricature of two approaches to the statement of the risk of a new technology or chemical. An extreme environmentalist might say that the risk is unity because we do not know that it is not. A captain of industry, and since the formaldehyde decision, I would add the judges of the Fifth Circuit Court of Appeals, might say that it is zero because we cannot prove that it is not. A more cautious analyst tries to find a number, with all its uncertainties, between these two extremes.

Medical men often use the word "risk" differently from what I do here. They include only attributable risk, or risk where dead bodies can be unequivocally counted. Toxicologists extend the idea to cases where dead mice can be counted. I believe even toxicologists restrict the use of the word too much. If they go further, as some do, and imply that we should only consider risks that can be easily calculated, then we miss most of the opportunities for improving public health.

We did not purify water because we saw dead bodies next to the water tap, but because we had indirect evidence of disease. We did not install good sanitation because we could count the bodies in the privy, but from general principles.

Yet to these two steps can be attributed a large part of the increase of expectation of life from less than 50 years a century ago to 79 for nonsmokers today.

Federal agencies regularly try to regulate some risks and ignore others of greater magnitude. The carcinogen assessment group—CAG—of EPA only estimates risks when an animal bioassay gives a statistically significant answer and implicitly ignores untested or badly tested chemicals.

Fortunately, they are not consistent.

In the drinking water standards, bromoform, not yet showing statistically significant results in an animal bioassay, is regulated, but only as much as chloroform.

There is a proposal to regulate the industrial solvents, tricholorethylene and perchlorethylene, more stringently than chloroform, even though they are less toxic and less carcinogenic.

The FDA regulates aflatoxin B1 in peanuts, but not very much; they tried to regulate saccharin, but Congress said no, and have given a hard time to hair dye manufacturers and makers of plastic bottles out of which carcinogens might leach. But the order of hazard is the order I have given with aflatoxin the worst.

When the EPA regulated EDB, they did so on the basis of a document, position document No. 4, which is one of the worst documents I have ever seen. The risk numbers have no quoted errors, and change throughout the report.

Worse still for a regulation under FIFRA, the risks of the alternates to EDB are not discussed, and in February there was published the first bioassay of one alternate—methyl bromide.

It seems to be more carcinogenic than EDB. I do not know whether EDB should be banned or not. I do know that the banning is unjustified, the net effect may be detrimental to public health.

The EPA recently promulgated regulations on the ambient air particulate standard. Their approach seems to be to set a standard just below that at which dead bodies have been seen and tentatively attributed. There is no estimate of risk in the approach used there, in spite of Mr. Ruckelshaus' appeal for risk assessment.

How will this bill help? Ideally it will bring one or two sample cases that will have peer reviews; with full discussion among scientists, risk assessors, and the public on what risk means; how to express it in context; how to take account of uncertainty; how to include differences in value judgments.

Why do some people oppose risk assessment?

I believe it is because they see a misuse of it. This bill should help to highlight cases of correct use and of misuse. An environmentalist sees an industrialist stating only the attributable risk and ignoring the unknown and uncertain. The Fifth Circuit Court of Appeals also demanded an unreasonable degree of proof from the Consumer Products Safety Commission and refused to allow the formaldehyde ban to stand. On the other side, an industrialist sees environmentalists—and some regulatory agencies—setting an unreasonably low level below which a risk is too small to be considered, yet only on arbitrarily chosen issues.

This Delaney clause mentality will be improved by a proper comparison of risks.

Still another group might see a risk assessment erroneously used to justify the continuation of a policy which is particularly risky to them, though not to others. To see how risks can be differently calculated by different groups, I give the example of the risk of being mauled and killed by a bear in Glacier National Park.

According to my data, five people were killed in 15 years. This gives a risk averaged over all Americans of 5/15 × 1/225,000,000 per year, 1/700 million or 1.5/ billion.

By most standards, this is negligible, and indeed I doubt that the President of the United States worries about it much. But the risk averaged over 2 million park users is 5/15 × 1/2,000,000 or 1/6 million per year, or 1.6/10 million.

This is bigger, and the Park Service worries about it, but not much.

Now let us average it over those who go into the back country, the backpackers, for all the deaths were among this group.

There are 20,000 backpack permits issued in 1 year, so the risk now becomes 5/15 × 1/20,000. This is one in 60,000 or 1.6×10^{-5}/ year. This is not enough to stop my wife and me from backpacking, but we did worry about it, and wore bear bells. Four out of five of those who died were among the 1,000 employees of the park concession: their risk is now 4/15 × 1/1000 or 1 in 4,000 per year. This risk is quite a large risk and should not be ignored.

Someone concerned about this large risk might well be annoyed if someone constantly tells him that when averaged over all society, the risk is very small.

We have done very well in the last century; the expectation of life at birth has risen from under 50 to 79 for nonsmokers. This has been done by some generic solutions—pure water and good sanitary engineering and by attention to detail. But in most cases, there was no specific health hazard; no one waited to find out which disease was caused by which bug in the water. We knew there was a risk and acted accordingly.

But we did not go overboard. We could have had purer water, no chloroform, by distilling it. That is possible, but excessive, and we wisely stopped short and had enough money to provide pure water for everyone and not just a select few.

That is what responsible risk analysis in risk management is all about.

[The prepared statement of Dr. Wilson follows:]

(short)

Testimony to be given to
the Committee on Science & Technology
U.S. Congress, Tuesday June 5, 1984

Richard Wilson
Mallenckrodt Professor of Physics
and Chairman, Physics Department
Harvard University, Cambridge, MA 02138

Mr. Ritter, Congressmen, Ladies & Gentlemen, [it is an honor and privilege to be asked to talk to you today about the proposed bill H.R. 4192.] ①

This is a risky world we live in. Hazards to public health and safety exist on all sides. In fact, if we add up the risks to which we are exposed over time - supposing we can calculate these properly - we must get unity, because all of us die and we die only once. What we are interested in, of course, is the risk of early death.

The word risk, and the phrases risk analysis, risk evaluation, risk management, and risk assessment are now popular in the federal government. The EPA administrator William Ruckelshaus in particular has popularized the concept. But is the concept properly used? In many cases it is not. Like many another concept, it is seized upon by individual pressure groups and twisted to suit their ends. This then leads other pressure groups to damn the concept, when they should damn the misuse.

Dr. Crouch and I wrote an article for the student paper "Governance". We originally titled it "Risk assessment - everyone talks about it, no one uses it" but the editors changed the title to "Uses and misuses of risk assessment."[1]

[Risk implies uncertainty, and when it is uncertain whether a chronic health hazard exists, there is a risk that it does (a risk of a risk), and therefore a risk to health. All too often this risk of the unknown is ignored.

I illustrate by a caricature of two approaches to the statement of the risk of a new technology or chemical. An extreme "environmentalist" might say that the risk is unity - because we do not know that it is not. A captain of industry, and since the formaldehyde decision I would add the judges of the 5th Circuit Court of Appeals, might say that it is zero, because we cannot prove that it is not. A more cautious analyst tries to find a number - with all its uncertainties - between these two extremes.

Medical men often use the word risk differently from what I do here. They include only attributable risk, or risk where dead bodies can be unequivocally counted. Toxicologists extend the idea to cases where dead mice can be counted. I believe even toxicologists restrict the use of the word too much. If they go further (as some do) and imply that we should only consider risks that can be easily calculated, then we miss most of the opportunities for improving public health. We did not purify water because we saw dead bodies next to the water tap, but because we had indirect evidence of disease. We did not install good sanitation because we could count the bodies in the privy, but from general principles.

Yet to these two steps can be attributed a large part of the increase of expectation of life from less than 50 years a century ago, to 79 for nonsmokers today.[2]

Federal agencies regularly try to regulate some risks, and ignore others of greater magnitude. The carcinogen assessment group (CAG) of EPA only estimates risks when an animal bioassay gives a statistically significant answer, and implicitly ignores untested or badly tested chemicals. Fortunately, they are not consistent. In the drinking water standards, bromoform (not yet showing statistically significant results in an animal bioassay) is regulated, but only as much as chloroform. There is a proposal to regulate the industrial solvents trichlorethylene and perchlorethylene more stringently than chloroform, even though they are less toxic and less carcinogenic.[3]

The FDA regulates aflatoxin B1 in peanuts - but not very much; they tried to regulate saccharin (but Congress said no) and have given a hard time to hair dye manufacturers and makers of plastic bottles out of which carcinogens might leach. But the order of hazard is the order I have given with aflatoxin the worst!

When the EPA regulated EDB, they did so on the basis of a document, position document number 4, which is one of the worst documents I have ever seen. The risk numbers have no quoted errors, and change throughout the report. Worse still for a regulation under FIFRA, the risks of the alternates to EDB are not discussed, and in February there was published the first bioassay of one alternate - methyl bromide. It seems to be more carcinogenic than EDB. I do not know whether EDB should be banned or not. I do know that the banning is unjustified, the net effect may be detrimental to public health.[4]

The EPA recently promulgated regulations on the ambient air particulate standard. Their approach seems to be to set a standard just below that at which dead bodies have been seen and tentatively attributed. There is no estimate of risk in the approach used here, in spite of Mr. Ruckelshaus' appeal for risk assessment.

How will this bill help? Ideally it will bring one or two "sample" cases that will have peer reviews; with full discussion among scientists, risk assessors, and the public on what risk means; how to express it in context; how to take account of uncertainty; how to include differences in value judgments.

Why do some people oppose risk assessment? I believe it is because they see a misuse of it. This bill should help to highlight cases of correct use and of misuse. An environmentalist sees an industrialist stating only the attributable risk, and ignoring the unknown and uncertain. The 5th Circuit Court of Appeals also demanded an unreasonable degree of proof from the Consumer Products Safety Commission and refused to allow the formaldehyde ban to stand. On the other side, an industrialist sees environmentalists - and some regulatory agencies - setting an unreasonably low level below which a risk is too small to be considered - yet only on arbitrarily chosen issues. This "Delaney Clause" mentality will be improved by a proper comparison of risks.

Still another group might see a risk assessment erroneously used to justify the continuation of a policy which is particularly risky to them - though not to others. To see how risks can be differently calculated by different groups, I give the example of the risk of being mauled and killed by a bear in Glacier National Park.

According to my data, 5 people were killed in 15 years. This gives a risk averaged over all Americans, of 5/15 x 1/225,000,000 per year, 1/700 million or 1.5/ billion. By most standards this is negligible, and indeed I doubt that the President of the USA worries about it much. But the risk averaged over 2 million park users is 5/15 x 1/2,000,000 or 1/6 million per year, or 1.6/10 million. This is bigger, and the park service worries about it but not much. Now let us average it over those who go into the back country - the backpackers (for all the deaths were among this group). There are 20,000 backpack permits issued in a year, so the risk now becomes 5/15 x 1/20,000. This is one in 60,000 or 1.6 x 10^{-5}/year. This is not enough to stop my wife and I from backpacking. But we did worry about it, and wore bear bells. 4 out of 5 of those who died were among the 1000 employees of the park concession: their risk is now 4/15 x 1/1000 or one in four thousand per year. This risk is quite a large risk, and should not be ignored.[5] Someone concerned about this large risk might well be annoyed if someone constantly tells him that when averaged over all society the risk is very small.

We have done very well in the last century. The expectation of life at birth has risen from under 50 to 79 for nonsmokers. This has been done by some generic solutions - pure water and good sanitary engineering and by attention to detail. But in most cases there was no specific health hazard: no one waited to find out which disease was caused by which bug in the water. We knew there was a risk - and acted accordingly.

But we did not go overboard. We could have had purer water (no chloroform) by distilling it. That is possible but excessive and we wisely stopped short and had enough money to provide pure water for everyone and not just a select few. That is what responsible risk analysis in risk management is all about.

---

1) E.A.C Crouch and Richard Wilson. Uses and misuses of risk assessment.
Governance Spring 1984, p.10.

2) E.A.C. Crouch and Richard Wilson. Risk/Benefit Analysis
Ballinger 1982. This reference discusses the whole field.

3) L. Zeise, Richard Wilson and E.A.C. Crouch. The risks of drinking water.
Water Resources Research 19, 1359, 1983.

4) Richard Wilson Risks of EDB. Privately cirulated document.
Bruce Ames Leading article in Wall Street Journal.

5) See Richard Wilson. Traps and errors in risk analysis. Lecture in Washington D.C. 1981

Mr. Sive. I will not repeat word for word what is set forth in the main testimony, but try to make some brief comments within the 5 or even fewer minutes that we have to proceed.

As to the bill itself, I think it makes one basic assumption or one basic conclusion really, that in the field of risk assessment there is really nothing that can and should be done within the next 30 months, because it is only after 30 months of greater knowledge that something will be done after the recommendation called for by the coordinating agencies.

That is a very momentous decision and it gets back to the problem of how much knowledge we should have before we proceed to make a decision.

In my own view, I think 30 months is too long and I think if something has to be done about risk assessment by various agencies, we know enough now to make the political and social judgments.

Going beyond that, I think I give, as a citizen, not as any expert at all—going to the field in which I think there is some special qualification which is needed and that is, looking at risk assessments as part of the general administrative process, what I found lacking in the various discussions of risk assessment which I see lacking in the bill, lacking I think in the NIP report, is really considering risk assessments as a question, as an issue, perhaps an issue of law, perhaps an issue of mixed fact and law, the issue of this risk in a particular proceeding.

I do not use the word proceeding in the technical lawyer's sense, but by proceeding I mean the process of making a decision and I would suppose in this field or risk assessment many of the important decisions are licenses, permits, certificates.

Whether the process is one which is very close to a court process, a quasi-adjudicative process with formal testimony and cross-examination, the limitations to a record, et cetera, or whether it is a much less formal process, informal decisionmaking, there is a process before each agency which is spelled out by that agency's organic law or by the Administrative Procedure Act and by various principles of administrative law, some of which are set down in cases, and principles governing the judicial review of administrative action.

Now, the problem, which I don't see treated here, and I haven't seen treated elsewhere, is how you may pluck out a question of risk assessment, pluck it out of that process and use some different process or different body or agency to do that, how that may be done lawfully under the organic statutes of each agency, or their own regulations, and then assuming they do pluck that out, then how you fit that in with the regular course of decisionmaking in the proceeding.

That problem I have not seen addressed, and I think under the very broad definitions of risk assessment which we have here, so many questions would fall into that that if there is to be a plucking out of that question and handling of that by some other agency or in some manner outside of the regular proceeding, you complicate and extend and delay the final determination, whether the proceeding be adjudicative or whether it be informal.

Just one final comment concerning those proceedings. In my own experience, and I think this refers to risk assessment and risk evaluation problems too, the great debate of the last 15 years has really been between scientists and lawyers. Lawyers defend and protect their particular adversary process, or I think perhaps less so these days than years ago, and scientists look upon that adversary process as wasteful, as abusive, et cetera.

That is a fundamental question which I have seen in the various studies of decisionmaking involving science and law, and that is the fundamental question which must be addressed in risk assessment questions: What can and should be the process?

In that connection, I would conclude by simply stating, my own views, I think, have softened somewhat through the years, my views about the wisdom and the perfection of the adversary processes, as we lawyers know it. I think many of us have seen that that just cannot make certain kinds of important decisions including important risk assessment decisions.

I thank you for the opportunity of being here.

Mr. SCHEUER. Well, thank you very much for those thoughtful words, Mr. Sive.

As you have indicated, different statutes embody different judgments about the acceptability of certain levels of risk. Some statutes, for example, bar agencies completely from considering benefits while others require sort of a balancing act.

Do these differences in the statutory approach suggest to you that the procedures for assessing risks also must be flexible?

Mr. SIVE. Well, I think they must as a matter of law, because however we define risk assessment, that assessment is made by an agency, and the procedure and manner in which that agency proceeds is set forth in other laws, the organic law of the agency, general principles of administrative law, perhaps the agency's own regulations and certain aspects of the Administrative Procedure Act.

Mr. SCHEUER. I yield to Congressman Ritter for questions.

Mr. RITTER. I thank the gentleman, and I thank the two gentlemen for their very thoughtful testimony.

I would like to ask Dr. Wilson to comment on the idea of comparative risk assessment and Dr. Ahmed's comments that you just can't do it, it doesn't work. I notice in various of the books and writings of Dr. Wilson that you have gone to great lengths and exerted great efforts and pains to try and build this kind of perspective on hazards using or implying a comparative approach.

Could you comment on Dr. Ahmed's comments that it is not functional?

Dr. WILSON. Dr. Ahmed didn't explain his comment that it doesn't work, so I am not exactly sure why he is saying it. My experience is, when talking to other people as I have done a great deal to environmental groups and others, that trying to put risks in context for them not only does work, but I have been praised for doing it by the audience, and it is not easy because you want to try and find something. It is an anchoring point in the person's mind.

So I really have no idea what it is that Dr. Ahmed is concerned with because he didn't exactly say it. I would imagine one of his problems, however, might be that the idea that you would automatically only regulate those risks which are larger than other risks that you do not want regulated. We all know that one of the largest risks is, in fact, cigarette smoking and as you remember, you persuaded the chairman at a previous meeting to put out a cigar because of the risk he was undertaking.

But we decided not to have a major regulation of that in our society, and that does not mean that we should refrain from regulating smaller risks, other smaller risks, but we should be aware of what we are doing.

Likewise, in many risks we take in society voluntarily, I personally like hiking and climbing mountains. Some part of that, and particularly if I am careless about the weather, is comparatively dangerous. That doesn't mean to say that I will willingly allow other people to try to expose me to other unsafe practices which, when you compare the risks, are much safer than the ones I voluntarily take.

Provided one makes the comparisons with that sort of thing in mind, I think they could be extremely illuminating, and that is what I mean when it should be a proper comparison of risks, and I think that a very large part of the problem is a misuse of what one is doing and, in fact, one of the problems of leaving some of these entirely up to a single agency is the fact that the agency has its priorities and they will almost inevitably make a misuse.

And I would like to just comment that the actual business of estimating the risk should be able to be moderately common to all agencies, and there ought to be nuances on how they interpret certain points. Are they going to be slightly more pessimistic in the interpretation of the ranges of possible numbers in front of them which they would be in one case, or are they going to be more optimistic?

For example, if I am exchanging one pesticide for another, I have got to compare them on an equal basis. If I am really trying to find a brandnew pesticide, I should probably be extremely careful.

Mr. SCHEUER. Any further comments, Mr. Sive?

Mr. SIVE. I don't think so, unless there are further questions.

Mr. SCHEUER. Any further questions:

Mr. RITTER. No further questions.

Mr. SCHEUER. We thank the panel very, very much for their thoughtfulness and their testimony.

The meeting is adjourned.

[Whereupon, at 12:15 p.m., the subcommittee was adjourned subject to the call of the Chair.]

APPENDIX

ADDITIONAL MATERIAL FOR THE RECORD

98TH CONGRESS
1ST SESSION

H. R. 4192

To establish coordinated interagency research and demonstration projects for improving knowledge and use of risk assessment by those Federal agencies concerned with regulatory decisions related to the protection of human life, health, and the environment, and to provide for the establishment of a Central Board of Scientific Risk Analysis as a means of improving the scientific review and evaluation of risk analyses made by Federal agencies, with particular emphasis upon risk analyses involving issues of chronic health hazards.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 21, 1983

Mr. RITTER (for himself, Mr. MARTIN of North Carolina, Mr. FUQUA, Mr. WINN, Mr. WALGREN, Mr. GREGG, Mr. BROWN of California, Mr. SENSENBRENNER, Mr. YOUNG of Missouri, Mr. BOEHLERT, Mr. LUNDINE, Mr. DYMALLY, Mr. MINETA, Mr. DURBIN, Mr. MACKAY, Mr. BLILEY, Mr. TALLON, Mr. WOLF, and Mr. ZSCHAU) introduced the following bill; which was referred to the Committee on Science and Technology

---

A BILL

To establish coordinated interagency research and demonstration projects for improving knowledge and use of risk assessment by those Federal agencies concerned with regulatory decisions related to the protection of human life, health, and the environment, and to provide for the establishment of a Central Board of Scientific Risk Analysis as a means of improving the scientific review and evaluation of risk analyses made by Federal agencies, with particular emphasis upon risk analyses involving issues of chronic health hazards.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

TITLE I—RISK ASSESSMENT RESEARCH AND DEVELOPMENT

SHORT TITLE

SEC. 101. This title may be cited as the "Risk Assessment Research and Demonstration Act of 1983".

FINDINGS AND DECLARATIONS

SEC. 102. (a) The Congress hereby finds and declares that—

(1) a number of Federal agencies have been mandated by law to protect, or provide information to protect, human life, health, and the environment;

(2) the Congress in writing the laws, and the courts in interpreting the laws, have often required Federal agencies to consider risk and ways of reducing risk in those agencies' efforts to protect life, health, and the environment;

(3) decisions by Federal agencies, legally mandated to protect human life, health, and the environment, often involve rules to reduce risk to human life, health, and the environment;

(4) such regulatory decisions involve scientific, economic, social, and philosophical considerations;

(5) these decisions must often be made even in the face of uncertainty and incomplete scientific and technical information;

(6) these decisions may involve an assessment of risks to human life, health, and the environment and a balancing of those risks against the economic and social consequences of controlling them;

(7) improving the quality of the scientific component of such decisions is an important aspect of securing the public's ability to properly weigh the social and philosophical values intrinsic in them; and

(8) analysis of the comparative risks to health and welfare can assist in setting public policy objectives and gaining public understanding of regulatory management decisions.

(b) Accordingly, it is necessary for Federal agencies—

(1) to use the best possible methods for securing information on, and an understanding of, the scientific bases for their regulatory decisions;

(2) to utilize such information and understanding, whenever appropriate, in the assessment of matters pertaining to decisions related to the protection of human life, health, and the environment; and

(3) to delineate, as specifically as possible, the scientific basis for agency decisions from their more subjective, judgmental aspects.

(c) Since the methods of risk assessment are increasingly relevant to regulatory decisionmaking, research and demonstration of such methods should be encouraged.

(d) A study of risk assessment needs to be made to learn what is known and what is not known about assessing risks in the face of incomplete scientific and other information;

(e) Risk assessment is basically a multistep process consisting first of a scientifically based risk analysis, which concentrates on the identification, probability, and consequences of risk, followed by a risk evaluation which is more judgmental in nature and concentrates on decisions defining acceptable levels of risk. Risk assessment will not provide a formula for setting public policies and making regulatory decisions; however, it may be a procedure by which the delineation in subsection (b)(3) is facilitated.

(f) Regulatory decisions concerning risk must usually consider alternative courses of action and may therefore involve comparative risk assessment. Better comparative risk assessment will improve the balancing of alternatives. Comparison of risks represents a means by which levels of risk can be presented to the public in terms which facilitate their understanding and appreciation of various regulatory alternatives.

(g) A variety of Federal agencies use the results from risk analyses to varying degrees in regulatory decisions. A systematic effort to improve the quality of risk analysis should be established to enable agencies to more effectively use risk analysis as an instrument in making regulatory decisions.

(h) Recent judicial decisions have demonstrated the need to further develop risk analysis to meet standards required by Federal courts for Federal Government actions.

PURPOSE

SEC. 103. In view of the findings and declarations set forth in section 102, it is the purpose of this title to provide for comprehensive and coordinated research and demonstration projects for the study of risk assessment and its relationship to the regulatory process.

DEFINITIONS

SEC. 104. For the purposes of this title—

(a) the term "risk" means the potential of a given action to cause unwanted, negative consequences to human life, health, or the environment;

(b) the term "risk analysis" means the process of quantification, as much as possible, of the probabilities of an identified risk;

(c) the term "risk evaluation" means the process of judging the acceptability of various levels of risk to individuals, society, or the environment;

(d) the terms "risk assessment" and "assessment of the risks" mean the total process, including both risk analysis and risk evaluation; and

(e) the term "comparative risk assessment" means a procedure in which the assessment of the risks associated with one course of action and the assessment of the risks associated with an alternative course or courses of action are compared with each other and with the kinds of risks people normally face in their individual lives; and

(f) the term "Federal agencies" means agencies within the Federal Government which are involved with regulatory decisions concerning human life, health, and the environment.

OBJECTIVE AND ESTABLISHMENT OF PROJECTS

SEC. 105. (a) The objective of the projects established under subsection (b) is to develop the necessary knowledge to—

(1) improve the use of risk assessment within the Federal agencies referred to in subsection (b)(2) and (b)(3), giving particular emphasis to the use of comparative risk assessment;

(2) develop a coordinated and systematic approach to the conduct and use of risk assessment by such Federal agencies;

(3) define criteria and standards to guide the development and use of risk assessment;

(4) identify research needed by such Federal agencies to improve the methodologies and use of risk assessment in regulatory decisionmaking;

(5) coordinate among such Federal agencies the use of common research results and information required for risk assessment;

(6) establish within such Federal agencies a means to promote an understanding by the public of those agencies' efforts to address risks to life, health, and the environment by expressing those risks in terms of easily understood, everyday experience; and

(7) facilitate public understanding of the nature of regulated risks and the means of their quantification.

(b) The President shall direct in accordance with the provisions of this title the establishment of coordinated projects which shall—

(1) be designed to achieve the objectives set forth in subsection (a);

(2) involve, where appropriate, Federal agencies responsible for regulatory decisions concerning human

life, health and the environment or providing information for regulatory decisions, including but not limited to, the Food and Drug Administration, the Environmental Protection Agency, the Occupational Safety and Health Administration, the Food Safety and Inspection Service of the Department of Agriculture, the Nuclear Regulatory Commission, the Department of Energy, the Consumer Product Safety Commission, and the Department of Transportation; and

(3) involve, where appropriate, the Federal agencies with basic and applied research programs applicable to the improvement of risk assessment.

(c) The President shall designate an agency or agencies to coordinate the projects.

(d) The coordinating agency or agencies designated under subsection (c) shall present to the Congress within twelve months after the enactment of this Act a report which shall include—

(1) a review of the risk assessments presently being carried out within the Federal agencies specifically designated in subsection (b)(2) and the use of such assessments in the regulatory decisionmaking process;

(2) a review of the risk analysis research being carried out by Federal agencies specifically designated in subsection (b)(2), and the procedures within those

agencies for linking this research to the regulatory decisionmaking process;

(3) identification of specific areas of emphasis for research conducted within the Federal agencies specifically designated in subsection (b)(2), and recommendations for funding priority of research on risk assessment by other Federal agencies, including but not limited to the National Science Foundation and the National Institutes of Health;

(4) recommendations for a coordinating mechanism to transmit and share research results among Federal agencies, between Federal agencies and other public agencies, and between Federal agencies and private and nonprofit corporations and institutions;

(5) a proposal for the risk assessment demonstration projects to be carried out under section 107 within the Federal agencies specifically designated in subsection (b)(2);

(6) identification of the areas where the use of the results of a risk assessment is required, encouraged, limited, or prohibited by current law, regulation, or practice; and

(7) recommendations for increasing public awareness and understanding of risk.

(e) The agencies participating in this effort are encouraged to utilize independent scientific advice from recognized experts in risk analysis.

RESEARCH

SEC. 106. The Federal agencies specifically designated in section 105(b)(2) shall recommend to the coordinating agency designated under section 105(c) research required to meet the objectives stated in section 105(a).

DEMONSTRATION PROJECTS

SEC. 107. (a) Each of the Federal agencies specifically designated in section 105(b)(2) shall undertake a risk assessment typical of that agency, in accordance with section 105(d)(5). These assessments should utilize presently available information and techniques, or new developments where available, and wherever appropriate should include the following elements:

(1) Comparison of risk of alternative courses of action.

(2) Delineation between scientific and policy judgments.

(3) Description of the present roles, if any, of technical or scientific advisory boards with respect to risk assessment.

(4) Identification of specific assumptions, guidelines, models, and uncertainties.

(5) Identification of limitations placed on the assessment due to relevant scientific, organizational, and statutory constraints.

(6) Identification of specific tradeoffs posed in the particular risk assessment.

(7) Suggestions of how additional information, or changes in statutory language and organizational structure, could change the strategies chosen in risk assessment.

(8) Discussion of how comparative risk assessment could be utilized to make the public aware of the relevance of the decisions, including a consideration of factors such as voluntary versus involuntary nature of similar risks, manmade versus natural risks, and necessary versus unnecessary risks.

(9) Delineation of information concerning the different levels of risk to health and welfare among different groups within the population, including consideration of socioeconomic, geographic, and other pertinent factors, to assist in the equitable sharing of the risks and benefits (including those that can and cannot be quantified in monetary terms) to be realized from the regulatory process and the implementation of public policy.

(b) Such studies shall be completed within two years after the date of the enactment of this Act, and shall be available to experts in the field for critical peer review and to the public at large.

REPORT

SEC. 108. (a) The coordinating agency or agencies designated under section 105(c) shall issue a report to the Congress within thirty months after the date of the enactment of this Act, which shall include—

(1) a summary of the findings made in or pursuant to the report presented under section 105(d);

(2) a summary of the risk assessment activities conducted pursuant to section 107;

(3) recommendations for future research necessary to achieve the purposes and objectives of this title;

(4) recommendations for legislation needed to implement and facilitate the use of risk assessment within Federal agencies;

(5) recommendations for nonlegislative changes, including organizational changes, to implement a policy of risk assessment within Federal agencies;

(6) recommendations that will result in the improved transfer of risk-related research and information between Federal agencies and private and nonprofit corporations and institutions; and

(7) recommendations for improving and increasing public understanding and appreciation of risk and regulatory decisions.

(b) In the preparation of the report the coordinating agency or agencies shall seek advice and comment from organizations and representatives of both public and private interests, and any comments made shall be included in the final draft of such report submitted to Congress.

SEC. 109. Nothing in this title shall constitute an authorization for the appropriation of funds from the Treasury of the United States.

TITLE II—CENTRAL BOARD OF SCIENTIFIC RISK ANALYSIS

SHORT TITLE

SEC. 201. This title may be cited as the "Central Board of Scientific Risk Analysis Act of 1983".

FINDINGS AND PURPOSE

SEC. 202. (a) The Congress finds that—

(1) actual and potential chronic health hazards, and other similar hazards which could affect human life, health, and the environment, are of great and growing public concern;

(2) it is important that the public have confidence in the adequacy, consistency, and independence of the

scientific basis for Federal regulatory decisions which assess the risks of such hazards; and

(3) there is a need for a central board of independent scientists to develop and issue criteria to guide Federal regulatory agencies in making risk analyses of such hazards and to selectively review risk analyses that deal with unique scientific issues of national importance involving one or more of such agencies.

(b) It is therefore the purpose of this title to establish a means of achieving consistency and promptness in the scientific evaluation of risk analyses made by Federal agencies, and of ensuring the adequacy of the scientific basis for such risk analyses when they involve issues of chronic health hazards or other actual or potential threats to human life or health or to the environment.

DEFINITIONS

SEC. 203. As used in this title—

(1) the term "hazard" means an actual or potential carcinogenic, mutagenic, or teratogenic effect, or an actual or potential effect of reproductive or neurotoxicological disorder, or any other significant effect involving a threat to human life or health or to the environment;

(2) the term "chronic health hazard" means a hazard which poses an actual or potential risk to

human life or health, including a risk of carcinogenesis, teratogenesis, reproductive disorders, or neurotoxicological disorders, or any other hazard which has or may have similar long-term effects;

(3) the term "hazard assessment", means the evaluation of all valid biologic, toxicologic, epidemiological, and other data relevant to a potential hazard;

(4) the term "risk", with respect to any hazard, means the likelihood for realization of unwanted negative consequences from such hazard to human life or health or to the environment;

(5) the term "risk analysis" means the scientific process of evaluating data to identify hazards and related risks, and includes risk characterization and (to the extent feasible) the quantitative analysis of risk; and

(6) the term "Federal agency" (except as used in section 204(a)) means any agency within the Federal Government whose duties regularly involve the making of regulatory decisions which are based on risk assessments made to identify the effects or conditions referred to in paragraphs (1) and (2).

ESTABLISHMENT OF BOARD

SEC. 204. (a) An agency designated by the President is authorized to enter into a cost-plus-fixed-fee contract with the National Academy of Sciences (hereinafter referred to as the "Academy") to establish within the National Research Council a Board of Scientific Risk Analysis (hereinafter referred to as the "Board").

(b)(1) The contract shall provide that Board members shall be appointed by the Chairman of the National Research Council under the committee appointment procedures of the National Research Council and shall function in accordance with all the policies and procedures of the Council. In making such appointments, recommendations shall be solicited from organizations of professional scientists, faculties of colleges and universities, heads of Federal and State agencies, and distinguished members of the scientific community.

(2) The membership of the Board shall be composed of individuals qualified and distinguished by training and experience in the life sciences or physical sciences (such as biology, biochemistry, biostatistics, epidemiology, comparative metabolism/pharmacokinetics, medicine, veterinary and human pathology, industrial hygiene, and toxicology), including individuals with expertise relevant to the analysis of risk.

(c) The contract shall further provide that the Academy, through the use of the Board, shall—

(1) develop, issue, and (as necessary) periodically revise scientific principles and practices for risk analy-

ses, reflecting the current state of the art for the risk analysis process;

(2) selectively review risk analyses made by Federal agencies, or establish subpanels to review specific risk analyses;

(3) organize scientific workshops, hold symposia, and make recommendations to Federal agencies on research needed in the risk analysis field; and

(4) regularly consult with the Federal agencies which are or may be involved and provide reasonable opportunity for public review and comment.

REVIEW OF RISK ANALYSES

SEC. 205. (a) Whenever a Federal agency proposes to make a regulatory decision or take a regulatory action based on a risk assessment or assessments concerning a substance (or the use of a substance) which results or may result in risk of a chronic health hazard or other similar hazard, and such risk assessment or any of such risk assessments is determined by such agency to involve scientific issues which are of national importance, the agency shall submit the risk analysis portion of such risk assessment or assessments to the Director of the Office of Science and Technology Policy and request the Director to refer such risk analysis to the Board (along with all of the relevant scientific information and data) for review under this section. If the Director and the Academy jointly concur with the determination of the agency under the preceding sentence, a public notice shall be placed in the Federal Register by the Director setting forth the requested referral and the reasons therefor and he shall submit such risk analysis to the Academy in accordance with the agency's request.

(b) Whenever a risk analysis is referred to the Academy under subsection (a), the Academy shall, through the Board or such subpanels of the Board as the Academy may create, expeditiously review such analysis, taking into account the available relevant scientific evidence relating to or bearing upon the risk analysis involved. The Academy shall keep a record of the actions taken and proceedings conducted in the course of any such review, and shall make such record reasonably available for public inspection consistent with the public access guidelines of the Academy.

(c) At the time of the referral of any risk analysis to the Academy for review under this section, and after consultation with the agency requesting such referral, a timetable (ordinarily not to exceed three months) for the review shall be submitted by the Academy to the Director of the Office of Science and Technology Policy, who shall place in the Federal Register a public notice of such timetable, including an invitation for public scientific input on the issues of concern to be reviewed, a statement concerning the schedule for such review, a summary of the agency's risk analysis, and a list of the relevant scientific information and data submitted under subsection (a). The Academy shall submit to the agency and make publicly available a written report on the analysis which was referred to the Academy for review.

NONBINDING EFFECT OF ACADEMY REPORTS

SEC. 206. Neither the criteria set forth in the risk analysis guidelines of the Academy nor the reports on the reviews carried out by the Academy under the provisions of this title, nor the analyses and findings included in such reports, shall be binding on any Federal agency; but if any Federal agency fails to adopt such criteria, or if the agency whose risk assessment is involved fails to adopt and act in accordance with any such guideline or finding, such agency shall publish in the Federal Register a complete explanation and justification of its reasons for such failure.

MISCELLANEOUS PROVISIONS

SEC. 207. (a) In the performance of its functions under this title, the Academy and persons acting on the Academy's behalf shall at all times maintain the confidentiality of trade secrets and of privileged or confidential commercial information. The members of the Board and the members of any subpanel of the Board shall be subject to the same conflict of interest and disclosure requirements that govern the appointment and selection of committees within the National Research Council.

(b) Neither the Academy nor any person acting on behalf of the Academy shall be liable for personal or property injuries caused in carrying out the requirements of this title.

AUTHORIZATION OF APPROPRIATIONS

Sec. 208. There are authorized to be appropriated such sums as may be necessary to carry out the purposes of this title.

EFFECTIVE DATES

Sec. 209. (a) This title shall take effect on the date of the enactment of this Act, except that no guidelines shall be published under section 204(c)(1) and no risk analysis shall be reviewed under section 205 until twelve months after such date.

(b) Unless reauthorized for an additional period by a law hereafter enacted, the provisions and authorities of this title shall terminate five years after the date of the enactment of this Act.

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

February 9, 1984

The Honorable David A. Stockman
Director
Office of Management and Budget
Washington, D.C. 20503

Dear Mr. Stockman:

This is in response to your request for a report on H.R. 4192, a bill "To establish coordinated interagency research and demonstration projects for improving knowledge and use of risk assessment by those Federal agencies concerned with regulatory decisions related to the protection of human life, health, and the environment, and to provide for the establishment of a Central Board of Scientific Risk Analysis as a means of improving the scientific review and evaluation of risk analyses made by Federal agencies, with particular emphasis upon risk analyses involving issues of chronic health hazards".

In summary, although we endorse most of the bill's objectives, we believe the bill is unnecessary. This Department, in cooperation with the Environmental Protection Agency, the Department of Labor, and the Consumer Product Safety Commission, is currently participating in the development of an Interagency Risk Management Council to address the major objectives of the bill. We find, in addition, the establishment of a Board of Scientific Risk Analysis troubling because of its potential for increasing administrative burdens on agencies while hindering the effective conduct of current regulatory review without any corresponding benefits.

H.R. 4192 would provide for coordinated interagency risk assessment research and demonstration projects. In addition, the bill would provide for a Board of Scientific Risk Analysis under the auspices of the National Research Council to review all risk analyses involving health hazards. This entire bill would sunset after five years.

We recognize the importance of coordinating interagency risk assessment and management processes among those Federal agencies concerned with regulatory decisions related to the protection of human life, health and the environment. We are also sensitive to the need for more explicit recognition of judgment inherent in some aspects of risk assessment and risk management decisions. We support increased opportunities for critical scientific peer review of risk assessment and management decisions. The Department is currently engaged in the development of an Interagency Risk Management Council, and we believe this effort will accomplish these objectives under current authority.

We currently consult outside experts for independent scientific review. For example, the Bureau of Foods at the Food and Drug Administration (FDA) routinely uses outside panels established under the auspices of the Federation of American Societies for Experimental Biology for periodic review of substances now generally recognized as safe (GRAS). Ad hoc panels were convened to evaluate the data on such substances as cyclamate, saccharin, Red No. 2 and Red No. 40. More recently, the Bureau has turned to a standing panel, the Board of Scientific Counselors of the National Toxicology Program. At the National Center for Drugs and Biologics, FDA often utilizes advisory panels composed primarily of scientists from academic medicine (including the National Research Council of the National Academy of Sciences) in its efforts to ensure the safety and effectiveness of prescription pharmaceuticals, over-the-counter drugs, and biologic products.

As noted by the National Academy of Sciences (NAS) in its study, Risk Assessment in the Federal Government: Managing the Process, simply separating risk assessment (or its review) from the regulatory agencies will not separate science from policy nor make risk assessment and management decisions more efficient. In any event, risk management decisions are ultimately policy decisions for which the proposed Board cannot be held accountable.

Other concerns raised by the provision for a Board of Scientific Risk Analysis stem from logistical problems. We are concerned that the Board may be ill-prepared to address differences in statutory and regulatory approaches such as those requiring or prohibiting economic analyses. Moreover, it may lack the broad range of disciplines necessary to perform reasonable analyses. These factors would constrain agency flexibility, to the detriment of effective regulatory response.

We therefore object to enactment of the bill.

Sincerely,

Margaret M Heckler

Secretary

university of washington
seattle, washington 98195

school of public health and community medicine

office of the dean, sc-30
(206) 543-1144

21 May, 1984

Dave Mallino
Industrial Union Department
AFL-CIO
815 16th Street NW
Washington, DC 20006

Dear Dave:

Sharon Morris informed me that you would like some current comments on the Ritter Bill, H.R. 4192.

You are welcome to cite my opposition to certain portions of the Bill in your testimony of June 5; I am not available to testify at that session, even if invited. My paragraph on this subject in the 30 November, 1983, letter to Sheldon Samuels still pertains.

Specifically, I believe Title I is much too broad, generates tremendous unproductive paperwork, and will surely be resisted by the Executive. The definitions, including the definitinn of risk assessment, are too breed, as well. The definitions and recommendatinns of the NAS/NRC Panel on Institutional Means for Improving Risk Assessment in the Federal Government are far preferable. Title I should be omitted.

I can support parts of Title II, the proposed Central Board of Scientific Risk Analysis, though--again--I believe the NRC Panel recommendations for a Board on Risk Assessment Methodology are much better. Specifically, in section 204(c), functions (1)"develop, issue, and (as necessary) periodically revise scientific principles and practices for risk analyses, reflecting the current state of the art for the risk analysis process" and (3)"organize scientific workshops, hold symposia, and make recommendations to Federal agencies on research needed in the risk analysis field"seem highly appropriate, desirable, and feasible. Functions (2) and (4) are very unwise. I cannot support a bill which requires the NAS to be inserted in the regulatory process on pending regulatory actions. The time limit (section 205c) of three months is impractical, and the requirement that the NAS/NRC become involved in detailed public comment procedures is poor public policy. The NAS should not be asked to take over clear responsibilities of the agencies, either to review current proposals or to manage public comment for the agencies. The scientific peer review mechanisms within the agencies should be strengthened for analyses of agency risk assessments. The NAS Board should be reserved for the plenty challenging role of evaluating and improving the methodologies for risk assessment and of recommending generic guidelines for consideration and use by the agencies.

Emblem "Soul Catcher" a Northwest Coast Indian implement used by shamans or spiritual healers to ward off spirits that brought physical or mental illness. These instruments were usually carved from the long bones of large animals and handed down from generation to generation

I hope these comments are useful to you. I would be pleased to have you insert these remarks in the Record.

Best wishes to you and Sheldon and Howard.

Sincerely yours,

Gilbert S. Omenn, MD

Gilbert S. Omenn, M.D., Ph.D.
Dean, School of Public Health
Professor of Medicine

National Cancer Advisory Board

National Cancer Program
National Cancer Institute
Bethesda, Maryland 20205

QUANTITATIVE RISK ASSESSMENT:
A REPORT OF THE CHAIR

Sheldon W. Samuels
Chairman
Subcommittee on Environmental
Carcinogenesis

February 2, 1983

Chairman
Dr Tim Lee Carter
Mr Richard A Bloch
Mrs Angel Bradley
Dr Victor Braren
Executive Secretary
Mrs Barbara S Bynum
Dr Ed L Calhoon
Dr Maureen M Henderson
Dr Robert C Hickey
Dr Geza J Jako
Dr Joseph Gale Katterhagen
Mrs Rose Kushner
Ann Landers
Dr LaSalle D Leffall
Dr William E Powers
Dr Janet D Rowley
Mr Sheldon W Samuels
Mr Morris M Schrier
Dr Irving J Selikoff
Dr Gerald N Wogan

BACKGROUND

The reactivation of the Subcommittee on Environmental Carcinogenesis, and my appointment as its Chair by Dr. Pitot and later by Dr. Carter, has come at a particularly turbulent period in the war against cancer. The turbulence rises from the rediscovery that a significant portion of cancer is a cultural artifact, i.e., not genetically based or inherent in natural occurrences but produced by society itself. That portion, therefore, is controllable only by painful social and personal change. Consensus on the magnitude of that portion does not exist and the range of estimates reflects a political polarization. Given our policy function and the synonymity of policy and politics, we are the appropriate body to deal with the cluster of issues of which quantitative risk assessment is only one.

The meetings we have had were, predictably, reflective of trenchant yet broad socio-economic and philosophic issues at the very base of public health policy. There is something especially significant in this regard about quantitative risk assessment. The questions raised in its consideration are answered only by making presumptions about the nature of operative science, the possibility of uncontaminated objectivity, social decision-making based on technical uncertainty, and the choice of methods in the face of the impossibility of satisfactory empirical verification.

Quantitative risk assessment, while it sounds "scientific," is a method understood only by the realization that it is a process of rough approximation regardless of the impression of axiomatic precision lent by its mathematic expression.

The Limitations

In a paper submitted to the Committee by Dr. Selikoff,* we have outlined for us some of the limitations:

- ° Expressed in static terms even though a dynamic situation addressed.
- ° Current estimates generally are restricted to those few agents for which reliable epidemiological data exists.
- ° Identification of agents and effects is obscured by latency factors.
- ° The spectrum of neoplasms is frequently unstudied since we focus on unique associations: angiosarcoma of the liver and vinyl chloride are examples.
- ° Fragmentary information on the number of people exposed and the general absence of dose measurement.
- ° The multiple sequential or concomitant exposure to interacting agents are not considered.
- ° Diagnostic uncertainties leading to underdiagnosis.
- ° Little is known about intrauterine exposures.

---

*Selikoff, Irving, J.: Multiple factor intervention in environmental disease: Potential for risk modification and risk reversal. Presented at the Symposium on Assessment and Perception of Health Risk, Royal Society of Canada and the Science Council of Canada, Toronto, October 18, 1982.

To the Selikoff list, I would add two others: the arbitrariness of the conceptual and mathematic models used in the actual calculation of risks and the unexamined value judgements made in the selection of a model to be used.

The statistical and stochastic biological models, summarized in the work done by Lester Lave for the American Petroleum Institute and submitted by them to the Committee, makes very clear the arbitrary nature of estimating the dose/response function in the current state of the science.

Lave's discussion reminds me of an observation by Bertrand Russell* that "...all deliberations and choice, all decisions as to policies demand the validity of causal series whose terms do not and will not exist. For the rational choice depends upon the construction of two causal series, only one of which can be made to exist. Unless both were valid, the choice would have no foundation. The rejected series consists of equally valid causal connections, but the events connected are not to be found among existents. Thus, all statesmanship and all rational conduct of life is based upon the method of the frivolous historical game in which we discuss what the world would be like if Cleopatra's nose had been half an inch longer."

---

*Russell, B.: Principles of Mathematics, 2nd Edition. New York, Norton, 1937, p. 475.

That "the events connected are not to be found among existents" may explain why Charles Brown, in advising the Committee, repeatedly made clear (with no contradiction by David Hoel or William Nicholson) that the models can not be verified. How, then, are they chosen? A series of value judgements are made reflecting the outlook and moral condition of the maker.

Utility

In the past, quantitative risk assessment has been used in various legitimate economic endeavors, e.g., for the insurance industry, but also in attempted cost/benefit analysis by regulators. Thus, many of its uses are in processes, like cost/benefit analysis, which many of us question methodologically and ethically as appropriate decision-making tools for environmental or health regulation.

Nevertheless, I would contend that it is a tool worth developing because its application is not limited necessarily to regulation. It could become an essential part of non-regulatory policies for the management of populations at high risk of cancer because of environmental exposure. As the submission from Paul Deisler (attached) points out, it can be used by a company in the setting of priorities in the absence of regulation. I have suggested its use as part of a trigger mechanism to select populations for special programs of intervention, including notification, medical screening and educational programs.

The minutes of the last meeting of the Committee, prepared by Dr. Adamson, reflects the status of our deliberation to date. I could submit it as a final report of the Committee, and forego further meetings, since it concisely defines and guides the process. At least one additional meeting is necessary, however, to take account of comments received after the last meeting from Dr. Deisler and Roy Albert. Both raise the issue of how to use animal as well as human data in the same estimation of human risk. While the use of such data necessarily increases the level of uncertainty in the assessment, the heuristic value of the work may also increase. We are engaged, after all, not in the determination of truth, but in its approximation.

# # # #

Rec'd 1-24-83 p.m. pey

Shell Oil Company

One Shell Plaza
P. O. Box 2463
Houston Texas 77001

Paul F. Deisler, Jr.
Vice President
Health, Safety & Environment

January 13, 1983

Dr. Sheldon W. Samuels, Chairman
Subcommittee on Environmental Carcinogenesis
National Cancer Advisory Board
Industrial Union Department, AFL-CIO
815 16th Street, N. W.
Washington, D. C. 20006

Dear Dr. Samuels:

I am responding to your letter of December 16 which was addressed jointly to myself and to Dr. Daniel Byrd of the American Petroleum Institute. Although I know Dr. Byrd well, I don't know why your letter was addressed to both of us since my original letter to you came solely from me. I therefore am not certain whether your question was addressed to him or to me, but I will attempt to respond to it, leaving it to him to respond separately if he feels he should.

In the material I sent you I addressed the question of the assessment and abatement of carcinogenic risk from two different perspectives, that of an organization such as a company acting to abate risk in the absence of regulation (or in the face of inadequate regulation) and that of a regulatory agency seeking to determine what regulation is needed, if any. The principal difference between the two cases is the capability each has of determining whether a given level of risk is acceptable or not.

A company or other similar individual organization is not in a position to judge the question of acceptability, however good a grasp it may have of the scientific information and analyses relating to a given case. The question of acceptability of any level of risk is a societal one, and regulatory agencies, as an instrument of society, are in a better position (however imperfect it may be) and have at least some mandate to make this judgment. Thus, while companies need and can construct for themselves systematic ways for estimating the level of risk and even of making statements about them and setting priorities for action with a pre-chosen goal for risk reduction in mind, they cannot decide whether a given level of risk is or should be called societally acceptable. My response to you is related solely to the perspective of a regulatory agency and its efforts to use quantitative risk assessment in its regulatory work.

First of all, it is my view that a risk assessment must be made at a given point in time, using all the information then available. While such an assessment may lead to conclusions as to what further research is needed in the future, the assessment is needed as part of the regulatory effort then underway and that effort frequently cannot await the outcome of research which may take years to conduct. The results of such research may cause regulations to be modified later, however, as a result of new regulatory actions.

Assembling and assessing the quality and applicability of available scientific data, the analysis of such data to determine whether a hazard (that is, the potential to do harm) is identified as being likely to exist, the development of the necessary extrapolations of the data (high to low dose and, for observations made with non-human species, from animal to man) or "hazard evaluation" are both scientific activities. Whether conducted by scientists in a research institute, by scientists serving on one of several types of panels, or otherwise, their activities are purely scientific in character. The results should be capable of withstanding review by scientific peers.

Similar assembly of information on the amounts, levels, distributions, routes, etc., of exposure humans may encounter is a scientific and technological activity, and the combination of this kind of information with the results of hazard evaluation is also a scientific and technological activity which should be carried out by appropriate scientific and/or technological people, working through or within appropriate organizational structures. The combination of the results of hazard evaluation with the results of the characterization of exposures leads, in a quantitative risk assessment, to statements of the ranges of risks that sets of exposed individuals may run together with statements of the uncertainties associated with such estimates of the ranges of risk. The state of the art of quantitative risk assessment today usually permits us to achieve no more than this kind of result and often not so much; even the estimate of the "most probable" risk, as a single, credible value relating to a given set of people and the exposures to which they may be subjected is usually not possible because of the uncertainty as to the extrapolation model to use. Nonetheless, this portion of the process of risk assessment must be performed by scientists and technologists who together cover the fields of expertise required, since the actions and judgments involved are purely scientific and/or technological in character.

With the results of the above efforts in hand, the regulator must now decide whether the ranges of risks are societally acceptable or not and, if not, what to do to decrease the levels of risk to the point -- considering many additional factors, both technological and otherwise -- of being judged acceptable. Typically, requests for public comment in writing or at hearings, together with feasibility and other analyses, provide relevant information for this judgment -- and it is a judgment -- to be made. In my view, a regulatory agency should be charged with and held accountable for managing the overall process (as distinct from making each and every kind of assessment or judgment) leading up to the final stage in which the acceptability of risk is judged and, in that stage, should be charged with making the judgment after pulling together all relevant scientific, technological and other factors. It is in an agency's interest to be sure the scientists and technologists are protected from a priori policy influences and to see to it that their results are independently attained in the best atmosphere of objectivity achievable. This assurance must be a management objective of an agency.

There are many ways to organize to achieve the above independence while ensuring that necessary communications take place. Indeed, for an agency to manage the overall process it is not even necessary for all parts of that process to be administratively part of the agency and, in some respects, there are advantages in administrative separation. The American Industrial Health Council (AIHC) has developed proposals illustrating how science can be best utilized by regulatory agencies, and I enclose an AIHC document dated October 30, 1981, which presents some of their views as of that time.

The role of research institutes, as such, in quantitative risk assessment is one which I touch on only indirectly in the materials I sent to you earlier. Clearly, research institutes working in this field have ample research to do. Such work ranges from chronic testing to establish facts or test hypotheses to the development of better test methods, of better understanding of mechanisms and metabolysis, and work on interspecies translation, as well as work needed to develop better dose-response models based on pharmacokinetic models. The utilization and interpretation of in vitro and in vivo tests and work in related fields such as genetics and immunology, to name only two, are all fit meat for research institutes, as is work on epidemiological methods, biostatistical techniques, etc. Not only is such work needed to advance the art of quantitative risk assessment beyond its current primitive and highly uncertain state, but such work also can produce information of direct utility, either directly or as a by-product, in renewed risk assessments for regulatory needs. I don't see a research institute, as such, having the conducting of risk assessments for specific regulatory purposes as a primary objective, though some of the scientists in such an institute might well become involved in the scientific stages of risk assessment described above. It is not beyond reason, either, to imagine risk assessment panels such as the AIHC propose being housed in and given tangible support from an appropriately organized research institute; whether one would do this would depend on a consideration of alternatives of which this is one.

I hope I have answered the questions you asked so as to be helpful to you. In summary, I answer the questions you pose in the last paragraph of your letter as follows:

1. ..."who should do such analyses" -- Scientists chosen on the basis of their qualifications and from the fields needed and who work in an atmosphere promoting objectivity and sound scientific independence, yet who can communicate as needed with scientists within the agencies to be sure the questions the agency has are fully posed and responded to (see the AIHC publication enclosed for specifics).

2. "Is it possible to be general enough in such analyses so as to conceptually and institutionally separate the analytic process from its

specific applications?" -- Yes, but not to the extent of having a kind of handbook of formulas available to accomplish this purpose. The "separation" can readily be made conceptually, it can be institutionalized, and the institutionalization will help to maintain the correct kind of separation-with-communication.

Very truly yours,

cc: Dr. Carter
Dr. Adamson
Dr. Byrd

MINUTES

Subcommittee on Environmental Carcinogenesis

National Cancer Advisory Board

November 15, 1982

The Subcommittee on Environmental Carcinogenesis, National Cancer Advisory Board (NCAB), met on November 15, 1982 in Conference Room 11A10, Building 31, National Institutes of Health, Bethesda, Maryland.

Members Present

Mr. Sheldon Samuels (Chairman), AFL-CIO
Mrs. Angel Bradley, NCAB
Dr. Tim Lee Carter (ex-officio), Carter Clinic
Dr. William Powers, Harper Grace Hospital
Dr. Peter Pruess, Consumer Product Safety Commission
Dr. Janet Rowley, University of Chicago
Dr. Gerald Wogan, MIT

Dr. Richard H. Adamson (Exec. Sec.), NCI

Members Absent

Dr. Elliott Harris, NIOSH
Dr. Allen Heim, FDA
Dr. David Rall, NIEHS
Dr. Irving Selikoff, Mt. Sinai School of Medicine
Dr. John Todhunter, EPA

Invited Guests

Dr. Donald Barnes, EPA
Dr. Robert Brandt, OSHA
Dr. Charles Brown, NCI
Dr. William Nicholson, Mt. Sinai School of Medicine

Others Present

Mr. Jerry Boyd, The Cancer Letter
Mr. Jeff Christy, The Blue Sheet
Dr. John Festa, American Paper Institute
Dr. David Howell, NCI
Ms. Inga Park, Department of Energy
Ms. Harriet Stern, Geomet Technologies

Opening the meeting, Mr. Samuels expressed the opinion that the subcommittee's work to date has been very fruitful. He said that the subcommittee has received documents from the American Petroleum Institute, among which is an excellent paper by Dr. Lester Lave. Mr. Samuels also mentioned that at the last meeting of the subcommittee. Dr. Lamb, an unscheduled speaker, had been permitted to deliver a talk whose duration was as long or longer than those which were on the agenda. However, there was a subsequent telephone call to Dr. Adamson from Mr. O'Leary of the Chemical Manufacturers Association, who felt that insufficient time had been provided for presentation of his organization's viewpoint. Dr. Adamson pointed out to Mr. O'Leary that, in his opinion, Dr. Lamb had been given ample opportunity to speak, even though he was an unscheduled speaker. Moreover, Dr. Adamson added that members of the public present at the meeting were free to express their views in writing to him as Executive Secretary within ten days, and that this time limit would be extended as necessary to permit Mr. O'Leary such an opportunity. Although Mr. O'Leary did not subsequently submit a written complaint, Drs. Powers and Hogan suggested that Dr. Adamson write Mr. O'Leary asking him if he wishes to make a formal complaint or if he considers the matter closed.

Mr. Samuels then summarized the accomplishments of the subcommittee's first two meetings, pointing out that a main theme has been that NIH should not be doing risk assessment with regulation in mind. He added that after the present meeting, he, Dr. Adamson, and any other members who wished to participate would develop a draft paper summarizing the subcommittee's findings and suggestions. He suggested that this paper be given to the members of the subcommittee for their comments and then submitted at the January meeting of the NCAB for the Board's consideration. after which the paper could be reworked and resubmitted to the NCAB for approval as a policy paper of the NCI.

Since there was general agreement with this plan, Mr. Samuels next introduced Dr. Charles Brown, who presented a preliminary definition of quantitative risk assessment that was developed as a result of the subcommittee's first two meetings. After extensive discussion, during which several modifications were made, the subcommittee agreed on the following definition:

> Quantitative Risk Assessment. The assessment of both hazard and exposure information for purposes of estimating the likelihood that hazards associated with the substance will be realized in exposed individuals or populations. This assessment involves two steps:
>
> (1) HAZARD IDENTIFICATION/CHARACTERIZATION (QUALITATIVE RISK ASSESSMENT)
>
> The characterization of toxicity to humans as determined from observations on human populations and/or from experimental systems;
>
> (2) QUANTITATIVE RISK ESTIMATION
>
> The process by which the risk of disease or death in a population exposed to a toxic agent is related quantitatively to the pattern

of exposure, including factors such as the intensity and duration of exposure. The quantitative process includes an estimation of uncertainties.

Since the definition of quantitative risk assessment was the first item on the subcommittee's draft paper, Dr. Nicholson suggested that the second item be the purposes beyond regulatory action for which quantitative risk assessment could be used. As an example, he pointed out that the apparent imminence of increased abestos-related cancer, and the potential litigation associated with it, place quantitative risk assessment in a social/economic role. Furthermore, this is a situation in which risk assessment also focuses attention on needs for research, surveillance, possible intervention, and treatment.

Mr. Samuels then suggested that the third item be consideration of the institutional arrangements of quantitative risk assessment: i.e., who is to do the work and what safeguards will surround the effort. He felt that there should be a separation between research and regulation, and that quantitative risk assessment should initially be done by a research establishment that has no regulatory function. He added that this does not preclude replication of this work by regulatory agencies.

In response to a question from Dr. Powers concerning risk assessment of low-level radiation, Dr. Adamson explained that the NIH was directed by Dr. Brandt, Assistant Secretary for Health, to consider how best to proceed with the development of radioepidemiologic tables that would enable a calculation to be made of the likelihood that a paticular cancer was caused by exposure to low-level radiation from fallout from U.S. weapons tests in the 1950s and early 1960s. A subcommittee of the DCCP Board of Scientific Counselors was subsequently appointed by NCI at the request of the Director, NIH, to develop the necessary plans to prepare the tables, but not to prepare the tables themselves. Dr. Adamson added that the tables will probably be developed by a group outside the NIH and will then be peer reviewed by another, independent organization.

Dr. Carter pointed out that the Centers for Disease Control (CDC) is a non-regulatory agency well-equipped to conduct risk assessment. Mr. Samuels agreed that CDC might be appropriate in many instances, but suggested that in a larger sense, the Surgeon General might marshal whatever resources available to him on an ad hoc basis to do risk assessment. In situations where originators of data are outside the research establishment, the Surgeon General might create a special committee to evaluate the data. All deliberations of this kind would be conducted as peer reviews and would take place at open meetings.

Dr. Powers noted that it is part of the purview of the National Cancer Advisory Board to recommend to the National Cancer Program such activities as the unbiased accumulation of data and other resources for use in cancer risk assessment, and that this information might eventually be made available as a resource to the public.

Mr. Samuels next suggested that the fourth item on the paper be the application and validity of research models with respect to human cancer, and that it include consideration of the nature, limitations, and role of scientific models used in risk estimation.

For the fifth item, Mr. Samuels proposed a reaffirmation that the terms "safe" and "safety" not be used in risk assessment, since they have no scientifically demonstrable basis. Dr. Powers suggested that the term "tolerable" might be more appropriate under certain circumstances.

Dr. Wogan recommended that the sixth item be a positive statement of the contribution of NCI research to risk assessment. Dr. Rowley felt that this should be expanded to include all research institutions which use such techniques as chromosomal aberrations, DNA-adduct formation, sister chromatid exchange, and analysis of urinary mutagens to contribute to risk assessment. Dr. Wogan also suggested that the contribution of such research initiatives as biochemical epidemiology be mentioned.

For the seventh item, it was suggested that the draft document reaffirm the NCI role in environmental carcinogenesis, including selection of compounds and methods of testing through NCI's representation on the Executive Committee of the NTP.

Dr. Nicholson proposed that the eighth and last item be a statement concerning the uncertainties of quantitative risk assessment, including the influence of the quality of underlying data and the power of negative studies. He also felt that any risk estimate should specify its meaningful biological limits: i.e., the range of biological consequences of a given risk.

Mr. Samuels added that while the draft document focuses specifically on the problems of assessing risks from carcinogens and carcinogenic processes, there should be no implication that the principles articulated in the document are limited only to risk assessment of carcinogens. To emphasize this point, Mr. Samuels suggested that the presentation to the subcommittee by Dr. Robert Tardiff on risk assessment activities at the National Academy of Sciences be referenced in the document, as well as a paper by Dr. DeNevers on setting exposure standards in various parts of the U.S. Government.

Finally, at Mrs. Bradley's urging, the subcommittee agreed that the draft document should be entitled "Policy of Risk Assessment of the Health Effects of Hazardous Exposures to Populations."

Since there was no further business to conduct, Mr. Samuels thanked the members of the subcommittee for their efforts and adjourned the meeting.

Richard H. Adamson, Ph.D.
Executive Secretary

Executive Secretary's Note: The following documents were provided at this meeting:

Agenda
Definition for Quantitative Risk Assessment

National Cancer Advisory Board

National Cancer Program · National Cancer Institute · Bethesda, Maryland

POLICY OF RISK ASSESSMENT OF THE HEALTH EFFECTS OF HAZARDOUS EXPOSURES TO POPULATIONS

A REPORT OF THE SUBCOMMITTEE ON ENVIRONMENTAL CARCINOGENESIS, NATIONAL CANCER ADVISORY BOARD ON QUANTITATIVE RISK ASSESSMENT

Sheldon W. Samuels
Chairman
Subcommittee on Environmental
Carcinogenesis

Chairman
Dr. Tim Lee Carter
Mr. Richard A. Bloch
Dr. Roswell K. Boutwell
Mrs. Angel Bradley
Dr. Victor Braren
Dr. Ed L. Calhoun
Dr. Maureen M. Henderson
Dr. Robert C. Hickey
Dr. Geza J. Jako
Dr. Joseph Dale Kalterman
Mrs. Rose Kushner
Ann Landers
[illegible]
[illegible]
[illegible]
[illegible]

Prefatory Note

Use of Terms "Safe" and "Cause"

The term "safe" implies freedom from harm and is not used in this document because the concept does not have a scientifically demonstrable basis. Because the term "cause" is commonly associated with the single cause-single effect paradigm which is not applicable in most analyses of biological phenomena, this report also avoids use of that term. The concept of "risk" and "risk factors" should be used both in public and scientific publications in discussions of all toxic agents or processes.

During the course of these meetings, the Subcommittee also had access to and discussed the following six reports:

a. Selikoff, Irving J.: Multiple factor intervention in environmental disease: Potential for risk modification and risk reversal. Presented at the Symposium on Assessment and Perception of Health Risk, Royal Society of Canada and the Science Council of Canada, Toronto, October 18, 1982.

b. "Risk Assessment in the Federal Government: Managing the Process." National Academy Press, Washington, D.C., 1983. (Available to the Subcommittee since March 1, 1983)

c. Tardiff, Robert G.: "Some Activities in Risk Assessment at the National Academy of Sciences." Presented to the National Cancer Advisory Board Subcommittee on Environmental Carcinogenesis, August 10, 1982.

d. de Nevers, N.: Human health effects and air pollution control philosophies. Lung 156: 95-107, 1979.

e. Hoel, David G., Kaplan, Norman L. and Anderson, Marshall W.: Implication of nonlinear Kinetics on risk estimation in carcinogenesis. Science 219: 1032-1037, 1983.

f. Principles for Evaluating Chemicals in the Environment. 1975, National Academy of Sciences, p. 83.

INTRODUCTION

The present report is essentially an expansion of the items the Subcommittee agreed upon during the November 15, 1982 meeting in response to five questions posed by the Chair:

(1) Definition of quantitative risk assessment (QRA) as distinct from qualitative risk assessment.

(2) Which models or paradigms of QRA have been, are or are likely to be heuristic in terms of data fit, testability and predictive experience?

(3) Is QRA practical in terms of data adequacy of both dose and effects?

(4) Are the regulatory issues which involve QRA separable from the scientific problems of QRA?

(5) Who should do QRA?

The Subcommittee on Environmental Carcinogenesis met four times (August 10, 1982; September 23, 1982; November 15, 1982; and April 25, 1983) to gather information and views for development of a policy on quantitative risk assessment to be adopted by the National Cancer Advisory Board (NCAB). During these four meetings, information was presented by invited speakers from academic medicine, the regulatory agencies, the National Institutes of Health (NIH), the National Academy of Sciences (NAS), and industry. Subsequent to these meetings, letters, reprints and information on various issues pertaining to quantitative risk assessment were mailed to the Executive Secretary and/or the Chairman of the Subcommittee and were made available to the Subcommittee. The meetings have been summarized in the minutes and reprints made available during the meetings were appended to the minutes. In addition, the meetings were summarized in an interim report of the Chairman given to the NCAB on February 1, 1983.

1. Quantitative Risk Assessment

Quantitative risk assessment is defined as the assessment of both hazard and exposure information for purposes of estimating the likelihood that hazards associated with the substance will be realized in exposed individuals or populations. This assessment involves two steps. The first is hazard identification/characterization (qualitative risk assessment), in which toxicity to humans as determined from observations on human populations and/or from experimental systems is characterized. The second step, termed quantitative risk estimation, is the process by which the risk of disease or death in a population exposed to a toxic agent is related quantitatively to the pattern of exposure, including factors such as the intensity and duration of exposure. In quantitative risk assessment it is essential that both hazard and exposure information be considered. The quantitative process also includes an estimation of uncertainties.

In evaluating the risk of exposure to a particular agent, the first step is to consider the qualitative evidence that the agent is likely to be a carcinogen in humans. This evaluation relies on information from a variety of areas, including epidemiology. Epidemiologic studies provide important information about carcinogenic effects in humans because they associate human cancer incidence with exposure to particular chemicals, industrial processes or lifestyle factors. Clinical case reports and descriptive studies are of interest, but case control and cohort studies are of greater value.

Another source of information on the carcinogenicity of chemicals is long-term animal toxicology studies, in particular the rodent bioassay. Identification of a substance as a carcinogen depends on showing that the test substance causes an increase in the incidence of tumors or a decrease in the latency period.

Additional confirmation of carcinogenicity is provided by positive results observed in more than one animal species, in more than one bioassay or in different laboratories, and the demonstration that the occurrence of tumors follows a dose-dependent relationship. In animal bioassay studies, factors considered include the increase in tumor incidence in the treated group compared to controls, the number of tumors diagnosed per animal, and the percentage of tumors at a given site which are malignant. Both historical and contemporary control tumor rates are compared with those in the chemically treated group.

Other relevant studies include elucidation of structure-activity relationships, studies on metabolites of the carcinogen, and characterization of chemical and physical properties of the compound. Additional information about carcinogenicity of a compound is also obtained through numerous other studies, including cell transformation, studies on binding to DNA, various genotoxicity assays, and metabolism studies, including those in which metabolism in species in which the long-term animal tests were conducted are compared with metabolism in humans who have been exposed. Most recently, human epithelial cells and tissue explants have been used to provide information on potentially carcinogenic chemicals.

The second step in quantitative risk assessment is exposure assessment, a procedure as important as hazard assessment. Significant progress has been made in mathematical modeling, data monitoring, and laboratory approaches for determining the behavior of chemicals in the environment. Exposure assessment is a highly complex activity because any analysis must take into account various routes of exposure, different concentrations, human activities, biological conversions, chemical reactions, environmental transport mechanisms, and analytical limitations in the ability to quantify chemicals at trace levels.

When hazard exposure and assessment are completed, the final step, quantitative risk assessment, can be performed. This process applies data from epidemiologic studies, from long-term bioassay studies, and from other sources to describe the relationship between dose of the substance and the probability of toxic response.

The dosage in animal bioassay studies is exaggerated to compensate for the necessarily small study size of animal test systems. In order to anticipate effects at low levels, based on what experiments revealed at higher dose levels, the dose-response relationship must be extrapolated into the low-dose region. This region may be orders of magnitude below the dose level used in laboratory studies. Extrapolation from these studies involves the use of various mathematical models. No single model can be universally accepted at the present time. The development and selection of models should be increasingly influenced by an expansion of our knowledge of underlying biological mechanisms, such as the interaction of carcinogen metabolites and DNA.

The end point in quantitative risk assessment of chemicals for carcinogenicity is a final review and evaluation of hazard and exposure information, taking into account the uncertainties known to exist. The amount and reliability of information available on the numerous parts of an assessment will vary from chemical to chemical. It is important to make decisions about a chemical without overemphasizing any single aspect of the assessment. In addition, it is frequently necessary to make decisions about a chemical when the information available about it is imperfect and/or incomplete.

These uncertainties (and the other uncertainties apparent at each stage of the risk assessment process) should be clearly and explicitly stated to assist the management of the risks under study.

Moreover, while we are confident that research will reduce the arbitrariness of the selection of assessment methods, it is not probable that the need to make value judgements will be eliminated. The nature of these judgements should also be clearly and explicitly stated.

2. Uses of Quantitative Risk Assessment

Although the most obvious use of quantitative risk assessment is by the regulatory agencies as one tool in the regulatory process, there are other uses, or potential uses, of quantitative risk assessment. Among these are management of populations at high risk of cancer because of environmental exposure to chemicals and physical agents (e.g., asbestos-related cancer and the economic and social response to it), its use by industry for voluntarily setting priorities in the absence of regulations, and its use by Government, labor and others to select populations for special programs of medical screening, education and intervention.

For any use, it must be understood that we are dealing with a primitive application of rough mathematical approximations using data usually generated for other purposes. Those who question the use of quantitative risk assessment for any purpose for most environmental agents make substantive arguments.

The Subcommittee believes, however, that the development and use of this method ought to proceed on the basis of its potential good. Meanwhile, those who manage risk should interpret results obtained using currently available methods of assessment with great caution.

3. Institutional Arrangements of Quantitative Risk Assessment

One question raised by the Subcommittee was who should perform risk assessment. There was general agreement among the members of the Subcommittee, invited guests, and representatives from the regulatory agencies that scientists who perform quantitative risk assessment should be chosen on the basis of their qualifications and should possess expertise in the areas under consideration. In addition, it was felt that while scientists who perform quantitative risk assessment should continue to work both in * research and regulatory agencies, an atmosphere which promotes objectivity and sound scientific independence should be created, i.e., one separated from the regulatory process itself.

The Subcommittee concurred with the NAS, which in its report on risk assessment recommended that the process of risk assessment and risk management should be separated. It was also the concensus that the research agencies should continue to try to improve the data base, improve techniques that quantify exposure levels and continue to develop mathematical procedures applicable to risk assessment. In addition, risk assessments, regardless of where in the Government and by whom they are performed, should be peer reviewed, made available to the scientific community and subject to comment by the Surgeon General (or the Assistant Secretary for Health).

Circumstances might arise in which a particular institution within the DHHS would have information pertaining to a risk assessment (e.g., bioassay data from the NTP, epidemiology data from the National Cancer Institute [NCI], exposure data from the National Institute for Occupational Safety and Health [NIOSH]) not available to other institutions or agencies. In such a situation, the Surgeon General (or the Assistant Secretary for

Health) should be responsible for marshalling whatever resources and individuals in the government are available to perform a risk assessment.

In situations where originators of data used by the government for risk assessment are outside the government research establishment, a special committee (similar to the Clearing House established in previous years by the NCAB with balanced representation for the assessment of NCI bioassays) should be established by the Surgeon General (or the Assistant Secretary for Health) to evaluate the data. Deliberations of this kind should be conducted in meetings open to the public (when legally possible) as peer reviews. Special attention should be given to avoiding conflicts of interest and for protecting proprietary information.

The peer review system in place within the National Institutes of Health is adequate for the purpose of supervising the integrity of the risk assessment process. When an assessment is challenged, however, a mechanism should be available and used in a manner that will not delay, unreasonably, the use of the assessment. We recognize the fact that the peer review system can fail. Therefore, the responsibility for dealing with challenges must be remanded to the most neutral mechanism; i.e., a panel of career full time civil servants subject to existing laws governing conflict of interest and access to public information.

4. The Application and Validity of Research Models

The quantitative assessment of human carcinogenic risk from exposure to environmental agents often consists of extrapolating evidence from effects observed under one set of conditions in one population group or biological system to estimate the magnitude of effects expected under a different set of conditions in the human population of interest. This extrapolation involves, in part, mathematical models of the carcinogenic process which are necessarily simplistic representations of a complex biological stochastic process.

One class of these models, dose-response models, are used to describe the presumed mathematical relationship between the level of carcinogenic exposure (the dose) and the magnitude of its carcinogenic effect (the response). These dose-response models fall into two general categories: (1) tolerance distribution models and (2) models based on quantitative theories of carcinogenesis or other toxic responses.

The biologic basis for the class of tolerance distribution models assumes that the toxic reaction to a particular stimulus is a deterministic process which depends upon an individual's "tolerance level;" a level of the stimulus above this tolerance will produce a specific, singular toxic response with certainty, whereas a stimulus level below this tolerance will produce no response with certainty. Because of variability (both biological and environmental) among members of the exposed population, their tolerance levels will vary, sometimes within quite wide limits, to produce a "smooth" dose-response relationship for the population as a whole. This simple deterministic concept of an individual's tolerance for a particular toxic agent is not likely to provide a reasonable representation of the mechanism of carcinogens which act directly on DNA at the cellular level. However, indirect carcinogenic action (e.g., stimulation of enzymatic action or cell proliferation) may be describable by such models for individuals.

Another class of dose-response models is based on the concept of "hit theory" applied to initiation of the carcinogenic process at the cellular level. Once the cell has been "hit," the process of carcinogenesis is assumed to continue independently of the carcinogenic exposure. These models are axiomatically developed from a theory of the interaction between particles and targets necessary to produce a biologic response. These models were originally derived to explain radiation carcinogenesis, but have also been used for chemical carcinogens.

A generalization of the single event hit theory which explains cancer initiation is the multistage, or multievent, theory which assumes that the carcinogenic process consists of a series of cellular changes. These cellular changes are assumed to be heritable, are characterized as being of slow and improbable occurrence, and may or may not be affected by the particular carcinogen in question. Once a cell has progressed through all the stages, i.e., it has attained its full malignant potential, it then proliferates to a clinically detectable tumor. Other exposure-related risk factors (e.g., proliferation of partially transformed cells) can also be included in the theory. Other theories, based on multiple cells, have also been proposed.

These quantitative theories of carcinogenesis have produced a variety of dose-response models which have different risk assessment characteristics. Each dose-response model is based on a number of critical assumptions concerning the carcinogenic process. A major limitation of these dose-response models is that their currently untestable assumptions have a significant impact on carcinogenic risk assessments, and without additional basic knowledge concerning the mechanism of action, pharmacokinetics, DNA-adduct formation, etc., any choice from among these models cannot be made with confidence.

5. The Uncertainties of Quantitative Risk Assessment

The uncertainties inherent in quantitative risk assessment are many and varied. High dose to low dose extrapolation is the single, most important source of this uncertainty. Assumptions concerning the relationship between exposure level and carcinogenic response are necessary for this extrapolation since the response rates at low dose levels are often too small to be accurately measured with limited experimental or epidemiologic sample sizes. A quantitative estimate of the risk at a particular low dose level is highly dependent upon the mathematical form of the presumed dose-response relationship; differences among models of 3-4 orders of magnitude are not uncommon. More accurate high-to-low dose extrapolations are not possible without knowledge of the mechanism of action, studies on DNA adduct formation and information on metabolic disposition of the particular carcinogen in question, since the dose-response relationship is likely to depend upon these factors.

Part of the mechanistic knowledge concerns pharmacokinetic information on the fate of the toxic agent once it enters the body. Nonlinear kinetics may be an important determinant of the nonlinear dose-response often observed in experimental animal studies conducted at high dose levels. A critical problem in the application of pharmacokinetic principles to low-dose quantitative risk assessment is the potential change in the pharmacodynamics as the level of the toxic agent decreases. The presence of saturation kinetics at high doses may pose problems in quantitative risk assessment based on high dose experimental results. As an example, the metabolism of inhaled vinyl chloride has been shown to be a saturable process which provides a possible explanation of the nonlinear dose-response observed in animal studies. The lack of relevant dose-related pharmacokinetic information adds another measure of uncertainty in quantitative risk assessment within a single species.

Quantitative risk assessment across species, commonly referred to as the mouse-to-man problem, involves potentially more uncertainties than risk assessment within a species. Methodologies for making this animal-to-man extrapolation rest, in part, on pharmacokinetic considerations of species similarities in absorption, distribution, metabolism and elimination of the chemical carcinogen as well as DNA adduct formation and DNA repair processes. Although no single experimental animal species mimics man in all respects relevant to the pharmacokinetics of a particular chemical, animal-to-man extrapolation is often made with the critical assumption that all the relevant biological parameters are the same in humans and animals. Unfortunately, often very little is known concerning interspecies variations among these biological parameters and these potential species differences can make interpretation of animal-to-man extrapolations both uncertain and arbitrary.

In addition, other sources of uncertainty in quantitative risk assessment include: (1) environmental and genetic heterogeneity and interaction; there are many environmental factors that one may be exposed to through occupation (e.g., asbestos), lifestyle (e.g., cigarettes), or of intrinsic origin (e.g., hormonal imbalances) which may affect one's response to a particular carcinogenic exposure; (2) differential effects for exposure rate and duration; the presumed relationship of risk to the rate and duration of exposure can have substantial consequences when quantitatively estimating risk from one exposure situation to another; experimental studies of dose fractionation have shown that no general relationship exists; (3) reliable epidemiological data only exists for a relatively few agents to which humans are exposed and generally there is an absence of dose measurement. Also little information is available on intrauterine exposure; (4) the identification of agents and effects is obscured by latency factors; (5) the spectrum of tumors is sometimes overlooked because of a focus on unique associations (e.g., vinyl chloride and angiosarcoma); (6) diagnostic uncertainties may lead to underdiagnosis; (7) quantitative risk assessment is expressed in static terms even though a dynamic situation is addressed and finally (8) qualitative factors such as data quality, multiple studies from different sources (e.g., chemical structure/activity and various "mutagenesis" tests), multiple tumors within a single experimental animal species, multiple experimental species/strains giving different qualitative and/or quantitative results, the combination of negative and positive studies, and competing risk all have a potentially important effect on quantitative risk assessment.

The current methodologies for the quantitative assessment of human carcinogenic risk--which can be heuristic in careful applications--rely on necessarily simplistic and currently untestable assumptions. However, as further knowledge of chronic diseases and toxicity mechanisms is acquired, this information should help provide a basis for more precise and more widely applicable quantitative estimates of the risk to humans of environmental carcinogens.

6. The NCI Contribution to Research Related to Risk Assessment

NCI contributes to the development of information on quantitative risk assessment through its activities in the area of information dissemination, by providing advice and expertise to regulatory agencies, and through its efforts in the field of chemical and physical carcinogenesis research, epidemiology, and most recently in the new area of biochemical and molecular epidemiology.

The NCI provides assistance in an informal way to regulatory agencies responsible for performing risk assessments by keeping their staffs abreast of new developments in the area of carcinogenesis research and risk assessment methodologies. This informal interchange involves providing the agencies with accepted journal articles, reports and summaries of research findings pertinent to risk assessment; it also includes conferences focusing on issues of importance to risk assessment which are attended by representatives from NCI, the Food and Drug Administration (FDA), NIOSH and other agencies.

A number of laboratory techniques have been developed or adopted by the NCI intramural research program and by other research institutions to augment classical epidemiologic studies. These techniques, which include cytogenetic studies to detect chromosomal aberrations, assessment of carcinogen-DNA adduct formation, studies of sister chromatid exchange, and analysis of urinary and fecal mutagens, can make potentially important contributions to the risk assessment process. For this reason, the NCI is placing a major emphasis on a new research area called "biochemical and molecular epidemiology." This new area of emphasis consists of multidisciplinary investigations into cancer etiology that combine epidemiological and experimental approaches. Included are efforts to incorporate already developed biochemical techniques into epidemiologic investigations and the further development and refinement of new experimental procedures into safe, accurate, reliable and informative adjuncts to human investigations. The primary goal of biochemical epidemiology is to identify individuals at high cancer risk by obtaining pathobiological evidence of (a) high exposure of target cells to carcinogens and/or (b) increased susceptibility due to inherited or acquired host factors.

Currently available techniques exist that would allow the utilization of biochemical measures to better characterize exposure to carcinogens, to serve as intermediate end points on the path to malignancy, to identify measures which halt or reverse this process, and to facilitate the risk assessment process. Included in these investigations would be the following: (1) efforts to evaluate body burden of chemical carcinogens in studies of occupational and general evironmental cancer risk factors; (2) sophisticated analyses of air, water, and biologic specimens for carcinogenic and mutagenic substances in conjunction with specific analytic studies; (3) evaluation of disturbances in immune function as they may relate to malignancies, particularly those of the hematopoietic system; and (4) investigation of the relationship between micronutrients and a variety of epithelial cancers. Advances in laboratory methods have been recently developed to be used in combination with analytical epidemiology to identify individuals at high cancer risk. These methods include: (1) techniques to assess specific host susceptibility factors; (2) assays that detect carcinogens in human tissues, cells, and fluids; (3) cellular assays to measure pathobiological evidence of exposure to carcinogens; and (4) methods to measure early biochemical and molecular responses to carcinogens.

Two examples illustrate the potential of this approach. The first is the use of drugs to probe carcinogen metabolism. Most carcinogens require metabolic oxidation to electrophilic reactants to exert their carcinogenic effects. Oxidation is generally via a family of cytochrome P450 enzymes that also metabolize endogenous substrates and many drugs. These enzymes are under genetic and environmental control and their oxidative activities vary widely among individuals. Indicator drugs are now known to be oxidized by specific cytochrome P450s that are also responsible for the activation of carcinogens; e.g., the antihypertensive drug, debrisoquine, may be a useful probe for predicting metabolic activation of aflatoxin B_1. Individuals who are rapid metabolizers of such drugs may also be at high cancer risk when exposed to carcinogens that are activated by the same cytochrome P450s as the indicator drug.

The second example is the use of ultrasensitive enzyme radioimmunoassay to measure carcinogen-DNA adducts. The covalent binding of the activated form of a carcinogen to DNA may be viewed as both a pathobiological dosimeter of environmental exposure to a carcinogen and as a predictor of an individual's metabolic balance between carcinogen activation and deactivation and his capacity for DNA repair. Ultrasensitive enzyme radioimmunoassays to measure carcinogen-DNA adducts are 100-fold more sensitive than radioimmunoassays and are now being used in pilot laboratory-epidemiology studies. A wide variation in the amount of this type of genotoxic damage has been found in high risk groups due to occupation (e.g., foundry workers and asphalt workers) or personal habits (e.g., tobacco smoking). Based on an extensive data base from studies in experimental carcinogenesis, individuals with high levels of carcinogen-DNA adducts may be at increased cancer risk.

Scientific opportunities generally arise when two or more research areas converge and/or advances in methodology occur. Research in the laboratory has recently provided us with both critical information on mechanism(s) of carcinogenesis and new technological advancements including those in molecular biology. Epidemiology has clearly demonstrated the importance of environmental exposure to carcinogens. It is now practical to integrate laboratory determinations into more classical epidemiological approaches to chronic disease. The potential of biochemical and molecular epidemiology to predict cancer risk on an individual and population sub-set basis, instead of a total population level, and prior to the onset of clinically evident cancer may represent a significant contribution to risk assessment.

The NCI is performing intramural research in this area and is supporting extramural programs through the traditional R01 grant mechanism and through issuance of Requests for Applications (RFAs).

7. The NCI Role in Environmental Carcinogenesis

The NCI's contributions to environmental carcinogenesis are diverse, and include providing staff expertise and advice to regulatory and other agencies and institutions, disseminating information, and performing and supporting research in the areas of epidemiology and chemical and physical carcinogenesis. The Subcommittee felt that these NCI activities in environmental carcinogenesis were appropriate and that they should be continued.

In the 1970's, the NCI pioneered a carcinogenesis testing program through which scientists established a standardized way to evaluate the carcinogenic activity of chemicals in mice and rats, which seem to be good predictors of chemicals carcinogenic in humans. Of the 30 agents for which there is human evidence that exposure is associated with cancer in humans, all (with the possible exception of arsenic) are risk factors for cancer in laboraory animals.

In 1981, the carcinogenesis testing program was transferred to the National Institute of Environmental Health Sciences (NIEHS) from NCI, an action which provides for direct management by the National Toxicology Program of the NIH components of the program. Nevertheless, the NCI maintains a significant level of involvement in the carcinogenesis testing program by nominating chemicals for testing in the bioassay program and by membership on the NTP Executive Committee, which selects the chemicals to be tested.

The NCI also provides advice and the expertise of its staff to other government agencies, including those with regulatory functions such as the FDA and the Occupational Safety and Health Administration (OSHA), in the evaluation of data for use in risk assessment. It provides assistance in an informal way to agencies by keeping their staffs apprised of new information and developments in the area of carcinogenesis research. A primary means for broad distribution of research results is the published literature, and the NCI routinely provides the agencies with accepted journal articles, reports and summaries of new research findings, and in several instances information has been provided prior to publication in the journal literature. In addition, scientists often present preliminary data at scientific meetings prior to publication of final results which may not be available until several months later. Other productive avenues of exchange include conferences convened to discuss particular issues of importance related to environmental carcinogenesis and attended by individuals from NCI, FDA, NIOSH and other agencies.

In addition, the NCI provides input to NIOSH on occupational and environmental carcinogenesis through members of the Environmental Epidemiology Branch of the Field Studies and Statistics Program, DCCP. Other NCI staff members serve on panels and committees organized by regulatory and other agencies. For example, NCI staff are members of the Interagency Testing Committee organized to evaluate chemicals covered by the Toxic Substances Control Act. Staff from the NCI also serve as members of the Task Force on Environmental Cancer and Heart and Lung Disease, and as members of the Task Force Planning Group which reviews and plans the activities of the Working Group meetings including preparation of annual reports for Congress.

Staff represent the NCI on the DHHS Committee to Coordinate Environmental and Related Programs (CCERP), originally chartered in 1973 as the DHEW Committee to Coordinate Toxicological Research Programs. This committee was established by the Assistant Secretary for Health as a multi-agency group to exchange information on environmental health, toxicology, and related programs. In addition to representatives from each agency in HHS that supports or conducts these types of programs, there are liaison representatives from the Consumer Products Safety Committee (CPSC), the Environmental Protection Agency (EPA), OSHA, Council on Environmental Quality (CEQ), Library of Congress, Department of Energy (DOE), National Oceanographic and Atmospheric Administration (NOAA), Department of Defense (DOD), and the National Science Foundation (NSF). The Committee meets regularly four to six times a year, although it may meet more frequently as the need arises to discuss urgent problems on which the Assistant Secretary or the Department may need advice.

The Interagency Collaborative Group on Environmental Carcinogenesis is an informational committee, chaired by a representative of the NCI's Division of Cancer Cause and Prevention, which serves as a forum for exchanging information among member organizations--NCI, NIEHS, the FDA, USDA, the CEQ, NOAA, the National Aeronautics and Space Administration (NASA), the Department of Transportation (DOT), NSF and others involved in environmental carcinogenesis research, risk assessment, and regulation.

The NCI also serves on a committee organized by the Office of Science and Technology Policy to develop up-to-date carcinogen science papers. These efforts will include the preparation of a paper on Cancer Principles, for the use and guidance of Federal agencies with the responsibility of making policy guidelines on potential or recognized carcinogens.

The NCI is also involved in developing collaborative activities related to environmental carcinogenesis. The cooperative projects on environmental/ occupational cancer are with other Federal agencies (NIEHS, EPA, NIOSH and OSHA), State agencies, and other institutions. The Division of Cancer Cause and Prevention, NCI, manages the NCI/EPA and NCI/NIOSH collaborative programs on environmental and occupational carcinogenesis. The concepts underlying these projects are reviewed by the Divisional Board of Scientific Counselors, and they are managed jointly by co-project officers from NCI and the EPA or NIOSH. Scientific findings from these collaborative efforts are summarized in annual reports and published in peer-reviewed journals.

The NCI also maintains a cooperative agreement with the International Agency for Research on Cancer (IARC) which supports a monograph series entitled "Evaluation of the Carcinogenic Risk of Chemicals to Humans." These monographs have become the international reference standard in this field. They are widely used by Federal research and regulatory agencies in the U.S. for the evaluation of environmental cancer hazards. Other information resources supported by the NCI include an IARC effort to identify and list in an annual bulletin all laboratories in the world involved in carcinogenicity testing, and preparation of the PHS-149 Report (Survey of Compounds which have been Tested for Carcinogenicity).

Research in chemical and physical carcinogenesis and in epidemiology is performed by NCI scientists in the intramural program, and extramural research in these areas is supported by the NCI through the traditional R01 and P01 grant mechanism. The NCI also utilizes the RFA mechanism for stimulating research in areas of particular interest; for example two RFAs were recently issued in the area of chemical carcinogenesis, one entitled "Interspecies Comparisons in Carcinogenesis," the other "Experimental Studies on Natural Inhibitors of Carcinogenesis." Epidemiologic studies performed or supported by the NCI are aimed at identifying groups at higher or lower risk of developing cancer. Results from these studies suggest that environmental and lifestyle factors are associated with the disease, and thus increase the possibility that a reduction in the incidence of cancer can occcur.

NATIONAL ACADEMY OF SCIENCES
2101 CONSTITUTION AVENUE WASHINGTON, D.C. 20418

OFFICE OF THE PRESIDENT

June 20, 1984

The Honorable James H. Scheuer
Chairman
Subcommittee on Natural Resources,
Agriculture Research & Environment
Committee on Science and Technology
U.S. House of Representatives
Washington, D. C. 20515

Dear Mr. Scheuer:

At a recent hearing held by your Subcommittee on risk assessment, you asked the National Academy of Sciences for its views on Title One of the bill, H.R. 4192. Title One addresses the issue of inter-agency coordination of Federal risk assessment and provides for demonstration projects to increase the understanding and use of the risk assessment process. As you know, the Academies' National Research Council at the request of the Congress prepared a report, published in 1983 entitled, "Risk Assessment in the Federal Government: Managing the Process." The findings and recommendations of that study are relevant to the provisions of H.R. 4192.

It is clear in reading Title One that much of its intent can, in principle, be accomplished under existing law. However, the wide variety of risk assessment activities of Federal agencies makes very difficult a comprehensive and coordinated approach to both risk assessment and its relationship to the regulatory system. Thus, a clear statement of Congressional intent and a coordinated approach to assessment and management of risks should be especially helpful. In this respect, the bill's objectives are commendable. It provides useful guidelines for improving both the scientific and policy aspects of regulatory decision making related to the protection of human life, health, and the environment.

Drawing upon the findings of the National Research Council's Committee on the Institutional Means for Assessment of Risks to the Public Health, I would, however, suggest several modifications in the proposed language of Title One. These suggestions were brought to your attention in the May 17 testimony of Dr. Joseph V. Rodricks, a member of our study committee.

We recommend that the definitions of risk assessment and risk management, as set forth in the National Research Council's report, be adopted for purposes of H.R. 4192. These terms increasingly have been accepted by the scientific community and have become common terms of usage in several regulatory agencies. Regulatory decision making requires a clear distinction between risk assessment and risk management. Both terms are defined in the report and, in our view, their adoption in H.R. 4192 would improve governmental use of risk assessment, and improve understanding among regulatory agencies and by the public. Other definitions in Section 104 of Title One would have to be adjusted to assure consistency with the new terminology for risk assessment and management. It is my understanding that these definitional changes are being considered by your Subcommittee, as well as by the sponsors of the bill.

Much of the subject matter of risk assessment identified for further research and demonstration projects by H.R. 4192 was considered by the NRC study committee. If H.R. 4192 is enacted into law, we would urge that agencies undertaking projects and studies relating to risk assessment draw upon the case studies and experience of our study committee in order not to duplicate that work. As Dr. Rodricks indicated in his testimony, aspects of the proposed demonstration program have already been examined by our Committee, including the means for making the risk assessment activities of the Federal agencies more consistent and understandable to the public and the rationale for distinguishing between risk assessment and management.

Although not considered in Title One of H.R. 4192, our report strongly urged the creation of an independent nongovernmental board on risk assessment methods to prepare recommended uniform guidelines and to provide information on advances in the state-of-the-art. The diversity of responsibility among Federal agencies suggests that this need would best be fulfilled through a neutral forum in which all interested parties can meet, exchange ideas, and identify differences. Such a neutral forum would neither displace nor compromise an agency's regulatory responsibility, nor would it substitute for activities by an individual agency needed to address risk assessment problems unique to its mission. We would urge that the Federal government constructively consider the establishment of an independent board as described in the National Research Council's report.

In summary, Mr. Chairman, the National Research Council views the approach taken in H.R. 4192 as providing a positive pathway for expanding our fundamental knowledge on risk assessment in a systematic manner. We are pleased to assist your Subcommittee in its deliberations on this proposed measure.

Yours sincerely,

Frank Press

Frank Press
President

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
RESEARCH AND DEVELOPMENT

Honorable James H. Scheuer
Chairman, Subcommittee on Natural Resources,
Agriculture Research and Environment
Committee on Science and Technology
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Administrator Ruckelshaus has asked me to thank you for your letter of April 23, 1984, requesting information to assist your Subcommittee in its consideration of H.R. 4192, the "Risk Assessment Research and Demonstration Act of 1983." We are enclosing our written responses to your ten questions.

In preparing our responses, the Environmental Protection Agency staff has conferred with your Subcommittee staff, primarily on the issue of definitions. As you know, H.R. 4192 defines risk assessment in terms of two components: risk analysis and risk evaluation. We would point out that the history of this issue is noted for its semantic confusion. Over the last year, EPA and, I believe, most of our sister agencies in health and safety regulation, have used the terms risk assessment and risk management as defined by the National Academy of Sciences (NAS) in its report: "Risk Assessment in the Federal Government." In this context, the NAS definition of risk assessment is roughly analogous to the bill's definition of risk analysis, and the NAS definition of risk management is roughly analogous to risk evaluation. NAS further divides risk assessment into four activities: hazard evaluation, dose-response assessment, exposure assessment, and risk characterization. The traditional EPA definition of risk assessment also fits more neatly into the NAS definition.

Therefore, we propose to use the NAS definition because it is consistent with all of our analyses over the last year. In addition, because the Agency's entire mission is, in essence, risk management, the use of the bill's definition in our answers to your specific questions would cover all the Agency's activities. I hope these distinctions are acceptable and useful to you and the Subcommittee.

Thank you for the opportunity to respond to you on this important issue.

Sincerely,

Bernard D. Goldstein
Assistant Administrator
for Research and Development

Enclosures

RESPONSES TO QUESTIONS POSED BY CHAIRMAN JAMES H. SCHEUER ON RISK ASSESSMENT, APRIL 23, 1984

QUESTION 1

List, and briefly describe, all uses of risk assessment within the Agency.

RESPONSE TO QUESTION 1

EPA uses risk assessment for five activities:

a. Setting priorities, in which risks are estimated and ranked for purposes of evaluating candidates for further regulatory action. One example is the assessment of risk from hazardous air pollutants by the Office of Health and Environmental Assessment and the Office of Air Quality Planning and Standards prior to consideration of listing these substances as hazardous air pollutants under Section 112 of the Clean Air Act.

b. Evaluating risks vs. benefits, in which both the risks and benefits from the use of particular chemicals are assessed and balanced. This action is typical of the large number of reviews conducted of pesticides (about 1500 per year) in which potentially hazardous chemicals are used for reduction or elimination of agricultural and household pests or disease-bearing organisms.

c. Assessing residual risk, such as the Agency's assessments of the risks of benzene emissions from fugitive sources or from coke by-product plants after the selected controls are in place.

d. Setting standards for which specifications are based on risks to human health or risks to the environment. For instance, the Office of Health and Environmental Assessment and the Office of Air Quality Planning and Standards review the National Ambient Air Quality Standards on a five-year cycle. The Agency recently proposed changes to the standard for particulates because of this periodic review.

e. Describing the seriousness of the public health situation. The assessment on the use of ethylene dibromide, leading to a proposed cancellation and emergency suspension of registration, is a good example of this activity.

QUESTION 2

Indicate the total number of "risk assessments" completed and in progress during the last 12 months. For such "risk assessments," indicate the total cost to the Agency, including separate figures for staff resources and consultant or contractual expenses incurred.

RESPONSE TO QUESTION 2

Nearly every program office in EPA uses risk assessment in its regulatory or decision-making processes. In the course of a year, between 3,000 and 3,500 documents falling under the above "risk assessment" activities are produced in EPA Headquarters and the Regions. They differ, both within and among programs, in the nature and depth of the risk assessments, in the technical approaches used for conducting them, in the way they are conducted (e.g., program staff, regional personnel, contractor, or Office of Health and Environmental Assessment), and in the amount of internal or external peer review that the assessments undergo before they are used in the decision-making process. Factors affecting these activities include the kind of risk that is characterized, the practical need for the assessment as a part of the decision process (e.g., comprehensive peer reviewed documents for hazardous air pollutants versus short analyses which are not peer reviewed for pre-manufacturing notices), the quality and amount of scientific data available, the amount of controversy surrounding the scientific issues involved, and the importance of the action that the assessment supports. About 1500 of the risk assessments support pre-manufacturing notice determinations under Section 5 of the Toxic Substances Control Act and about 1500 support pesticide registrations and re-registrations. Those remaining are more comprehensive documents, and about 100 of these support major regulatory decisions.

We are now in the process of determining the total cost for the Agency of these risk assessment activities during the last 12 months, and will be forwarding these figures very shortly.

QUESTION 3

Indicate the extent to which risk assessments conducted by the Agency include the elements set out in Sec. 107 (a) of Sec. I of H.R. 4192.

RESPONSE TO QUESTION 3

(1) Comparison of risk of alternative courses of action. We have interpreted this to mean alternative courses of action to reduce any one pollution source [see related element (6)]. To the extent that we can calculate quantitative dose-response curves, the risk of alternative courses of action can be explicitly estimated. When the hazard information does not lend itself to explicit quantification, estimates are still made to the extent possible.

(2) Delineation between scientific and policy judgments. This is the essence of the NAS distinctions between risk assessment and risk management. EPA has characteristically followed this distinction. Our scientific analyses come from the Office of Health and Environmental Assessment, and from the scientific units of the EPA program offices (which are generally organizationally separate from the policy units). The policy analyses are added later. In the wake of the NAS report, EPA has committed itself to making this distinction clearer whenever it is blurred.

(3) Description of the present role, if any, of technical or scientific advisory boards with respect to risk assessment. There are two such organizations: the Science Advisory Board (SAB) for most of the Agency's activities, and the Scientific Advisory Panel (SAP) in the Office of Pesticide Programs. Both advisory boards are used for risk assessment portions of major regulatory actions but do not participate in risk management decisions.

(4) Classification of specific assumptions, guidelines, models and uncertainties. It is our goal to ensure that these are explicitly stated in all risk assessments.

(5) Identification of limitations placed on the assessment due to relevant scientific, organizational, and statutory constraints. This is an element which confuses the NAS distinctions between risk assessment and risk management. At EPA, there are no limitations placed on the scientific assessment. Scientific, organizational, and statutory constraints are considered in the risk management phase and are generally explicitly stated in any analytical documents supporting that phase.

(6) Identification of specific tradeoffs posed in the particular risk assessment. This element is related to element (1). We have assumed this to mean tradeoffs from reduction of one risk with possible increases in other risks due to intermedia transfer, use of substitutes, etc. When a specific regulatory option analysis is considered, these considerations are taken into account. When they can be explicitly estimated, that estimate is generally included in the analysis. Otherwise, such tradeoffs are approximated.

(7) Suggestions of how additional information, or changes in statutory language and organizational structure, could change the strategies chosen in risk assessment. Again, this element blurs the distinction between the NAS definitions of risk assessment and risk management. At EPA, the risk assessments are scientific analyses only. The risk management phase discusses how the scientific information relates to the statutory language or other policy considerations.

(8) Discussion of how comparative risk assessment could be utilized to make the public aware of the relevance of the decisions, including a consideration of factors such as voluntary versus involuntary nature of similar risks, man-made versus natural risks, and necessary versus unnecessary risks. This element also relates primarily to risk management. The components are generally discussed in risk management documents.

(9) Delineation of information concerning the different levels of risk to health and welfare among different groups within the population, including consideration of socioeconomic, geographic, and other pertinent factors, to assist in the equitable sharing of the risks and benefits (including those that can and cannot be quantified in monetary terms) to be realized from the regulatory process and the implementation of public policy. This element, again, blurs the distinction between the NAS definition of risk assessment and risk management. At EPA, the risk assessment generally includes discussion of the risk to different, sensitive population groups, such as asthmatics, where that information is available. Geographic factors are also explicitly taken into account in exposure analyses. For example, the Agency routinely calculates, where pertinent, the maximum individual risk for a person living near the source of pollution. This inevitably includes geographic considerations. Other factors such as socioeconomic considerations, equitable sharing of risks and benefits, and other pertinent factors are considered in risk management documents.

QUESTION 4

Indicate the extent to which the agency makes its risk assessments, and any guidelines under which risk assessments are prepared, available to the public or to the scientific community.

RESPONSE TO QUESTION 4

A typical process for major risk assessments and guidelines includes review by selected outside scientists, public notice of the availability of the document, public comment, review by the appropriate advisory committee, and revision before publication. Furthermore, to the extent that the risk assessment is part of a regulatory decision, it is subject to public notice and comment.

QUESTION 5

Describe any efforts the Agency has made within the last two years to improve or expand the use of risk assessment within the agency, including any efforts to improve intra-agency coordination of risk assessments or the development of any guidelines or protocols for risk assessments.

RESPONSE TO QUESTION 5

EPA issued its first guidelines (carcinogen risk assessment) in 1976, followed by guidelines for assessing risks for water pollution (1980). It proposed guidelines for mutagenicity in 1980, and developed draft exposure guidelines, which it presented to the SAB in 1983. The Deputy Administrator has directed an accelerated revision and/or development of intra-agency guidelines leading to interim guidelines in six areas by mid-summer: cancer, mutagenicity, reproductive effects, systemic toxicants, chemical mixtures, and exposure assessment.

Another significant initiative just launched by Deputy Administrator Alvin Alm, establishes a Forum on risk assessment matters, ultimately reporting to him. We are concerned that -- even when we have more and better risk assessment guidelines -- there will always be a need to advance underlying scientific knowledge in each area, and evolve new approaches for risk assessments. The Forum will: (1) review specific risk assessments upon request of the Administrator, Deputy Administrator, Assistant Administrators, or Regional Administrators; (2) provide a mechanism of interchange on science issues in risk assessment; (3) advise the Administrator and Deputy Administrator on precedent-setting cases and important risk assessment issues; and (4) recommend revisions or updates to the risk assessment guidelines, as appropriate.

QUESTION 6

Describe any efforts the agency makes to coordinate its risk assessments or its risk **assessment** procedures with other federal agencies.

RESPONSE TO QUESTION 6

EPA has always participated in inter-agency efforts to develop common risk assessment procedures. To this extent, EPA participated in activities of the Inter-Agency Regulatory Liaison Group (1977-1981), and the work of the Organization for Economic Cooperation and Development.

Within the last year, Administrator Ruckelshaus has encouraged the formation of, and participation in, the Interagency Regulatory Management Council, whose members include EPA, the Occupational Safety and Health Administration, the Consumer Product Safety Commission, the Food and Drug Administration, and the Food Safety and Inspection Service of the Department of Agriculture. This group is working on five projects: guidelines for risk assessments for cancer and reproductive effects, as well as activities in biotechnology, formaldehyde, and solvents -- all of which contain risk assessment aspects.

EPA also recognizes the need for consistency in Agency handling of information from a public and scientific standpoint. Therefore, whenever a particular inter-agency problem occurs, an ad hoc group of the agencies will coordinate risk assessments. Recent examples include inter-agency efforts on EDB and dioxin.

QUESTION 7

Does the Office of Management and Budget (OMB) ever comment upon or review agency risk assessments at any time during the risk assessment process? If so, at what point(s) in the risk assessment process does such OMB comment or review occur? Are any records of such comments or reviews made by the agency, and if so, are they made available to the public or the scientific community? Under what legal authority does OMB comment upon or review agency risk assessments? What is the effect of an OMB comment on or review of an agency risk assessment?

RESPONSE TO QUESTION 7

Generally, OMB does not comment directly on risk assessment as we define it. On the other hand, under Executive Order 12291, OMB does review and comment on the substance of regulatory decisions. In this sense, OMB is dealing with the "risk evaluation" part of the definition of risk assessment in H.R. 4192, by reviewing the appropriateness of control targets and the acceptability of control costs incurred to reach those targets.

As part of these reviews, OMB may question the appropriateness of a given level of residual risk, or the costs of a particular control. Few of their comments or questions are given or responded to in writing, however. Records of OMB's oral questions are not routinely kept.

QUESTION 8

Provide any written documents which refer to any procedures or understanding by which OMB comments upon or reviews agency risk assessments. Provide, for the ten risk assessments most recently completed, all written documents which make any reference to any comment, review, or contact by anyone at OMB with respect to such risk assessments.

RESPONSE TO QUESTION 8

As stated in response to question #7, formal procedures for OMB/EPA interactions on risk assessment do not exist, and written correspondence of any nature is rare. We include as part of this response two documents that may, however, be of interest to the committee. These documents are: EPA's Standard-Setting for Toxic Pollutants (12/83) (specifically on arsenic and radionuclides) and The Regulation of New Chemicals Under the Toxic Substances Control Act (3/84).

QUESTION 9

Please indicate whether the answers to these questions have in any way been reviewed by, or commented upon, by anyone at OMB.

RESPONSE TO QUESTION 9

In conformance with the procedures outlined in OMB Circular A-19, these responses were submitted to OMB for review.

QUESTION 10

Indicate the extent to which the agency may be legally required to conduct a risk assessment, or otherwise consider risks or costs of proposed agency action, and indicate the legal authority for such requirement, whether by statute, court decision, executive order, or other authority.

RESPONSE TO QUESTION 10

EPA administers eight acts which have risk assessment aspects and also sets pesticide tolerances under the Food, Drug and Cosmetic Act. A recent analysis, Statutory Risk Assessment Criteria, January 1983, was prepared by the EPA Office of General Counsel. It contains a review of all of the statutory provisions. A copy is enclosed.

EXECUTIVE [illegible] THE PRESIDENT
OFFICE OF [illegible] T AND BUDGET
WASH[illegible] D.C. 20503

December 9, 1983

Mr. Milton Russell
Assistant Administrator
for Policy, Planning
  and Evaluation
Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Dear Milt:

The Environmental Protection Agency's proposed standards for sources emitting two hazardous air pollutants, radionuclides and inorganic arsenic, raise several regulatory policy issues of great importance. EPA has solicited comments on, among other issues, the appropriate role of risk assessment, cost-effectiveness analysis, and benefit-cost analysis in setting emission standards. The enclosed paper discusses these issues in some detail. Our main conclusions are summarized in this letter.

EPA's proposed standards for these two pollutants would reduce the expected incidence of cancer by an estimated 4.06 cases per year at an annual total cost of $27.1 million. An alternative regulatory strategy would be to apply EPA's proposed control requirements only to those plants where the effectiveness of such controls would be relatively high; this alternative would lessen cancer incidence by 3.92 cases annually (96 percent of the expected reduction under EPA's proposal) at a cost of $7.4 million per year (27 percent of the expected cost of EPA's proposal). Going beyond the alternative strategy and extending controls to the remaining plants covered by EPA's proposed standards would achieve an estimated further reduction in cancer incidence of only 0.13 expected cases per year at an additional cost of $19.7 million per year.

Most of the public health gains from reducing these emissions can be achieved, in other words, by regulating a particular subset of the plants covered by EPA's proposed rules. This is because plants vary substantially in the nature of their production processes, the level of control already in place, and the population density in their immediate vicinity. As a result, the likely effectiveness in terms of public health gains of further control of these emissions varies across plants by several orders of magnitude.

The environmental policy advantages of greater attention to risk reduction in relation to control costs are clearly evident in the case of EPA's proposed standards for sources emitting inorganic arsenic. The proposed individual source controls have not been set with much regard to joint consideration of public health gains and control costs. As a result, the range across plants of compliance cost per cancer avoided is extremely wide: $7 million to $1.3 billion.

Greater emphasis on likely reductions in exposure and health risks in the standard-setting process would lessen such extreme variation and improve the standards. The following recommendations to that end are discussed more fully in our paper:

-- Risk assessment information is not now used by EPA at all stages of its standard-setting process; we believe it can and should be.

-- Not considering risk data in setting "Best Available Technology" standards has unfortunate consequences. The likely public health gains per dollar of expenditure resulting from EPA's regulatory decisions appear to vary across sources by a factor of more than 2000. The expected reduction in cancer incidence ranges from less than 0.001 to 2.000 expected cases avoided per million dollars of compliance expenditure. At some plants, EPA expects compliance with the proposed standards to yield public health improvements that are exceedingly small. We recommend consideration of the alternative regulatory strategy referred to above which, through greater attention to relative effectiveness, could achieve most of the expected public health gains at one-third of the cost or less.

-- EPA's initial step in standard-setting identifies source categories posing a "significant" public health risk. We question the usefulness of this step as EPA has employed it in the past and see no clear pattern in its application (such as a common de minimis cutoff risk level). If EPA decides to retain this step, we recommend selection of numerical criteria for de minimis risk levels.

-- To the extent that risk information is considered in setting standards, EPA has asked for comment on how individual risk should be measured. In our judgment annual individual risk is a far better measure for these purposes than maximum lifetime risk.

-- EPA also has requested comment on how it should take into account aggregate population risk as distinct from individual risk. We believe population risk is the better measure of the likely public health gains of regulation. Separate consideration of individual risks is necessary only where such risks are unusually high.

Sincerely,

Christopher DeMuth
Administrator for Information
and Regulatory Affairs

Enclosure

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

December 1983

EPA'S STANDARD-SETTING FOR TOXIC POLLUTANTS

A. Introduction

The Clean Air Act requires the Environmental Protection Agency to establish national emission standards for hazardous air pollutants. Section 112 of the Act requires that EPA first "list" a pollutant as hazardous, and then set emission standards for industrial plants emitting the listed pollutant. By the end of 1980, EPA had listed seven pollutants as hazardous and set or proposed plant emissions standards for five of them. EPA recently proposed standards for plants emitting the remaining two pollutants--inorganic arsenic and radionuclides. 1/ This paper considers the central policy issues raised by EPA's standard-setting approach in these proposed rules.

EPA's preamble to its proposed rules for inorganic arsenic and radionuclides outlines the following three-step approach for establishing standards for hazardous air pollutants: 2/

-- Categories of pollution sources are classified according to whether they pose a "significant

---

1/ See FR 15076 and 48 FR 33112.

2/ See 48 FR 15076 and 48 FR 33112. EPA also has outlined this three-tiered standard-setting process in a draft staff paper describing a process for evaluating and controlling toxic pollutants. U.S. Environmental Protection Agency, Proposed Process for Evaluation and Control of Toxic Pollutants, External Staff Draft, March 23, 1983.

risk" to public health. In making such a determination, EPA considers that a source category poses a "significant risk" if there is a strong likelihood that it emits a carcinogen and that individuals or the general population receive significant exposure to the substance emitted by the source category.

-- A source category judged by EPA as posing significant public health risks is then evaluated to determine the current level of control and the level of control constituting Best Available Technology (BAT) for plants or facilities in the source category. EPA's determination of BAT takes into account such factors as the potential for improved control, the economic effects of additional control requirements on the source category, and the age and remaining useful life of the facilities.

-- EPA determines whether the public health risks posed by the residual emissions of a source category would be unreasonable after installation of BAT controls. In making this determination, EPA considers the likely additional reduction in public health risks, the economic effects, and other effects of regulatory alternatives that are more stringent than the selected BAT requirements.

We think there are important shortcomings in this process arising in large measure from the way in which EPA chooses to use--and not to use--risk assessment information. 3/ The critical step in this process is EPA's BAT approach to standard-setting. This approach explicitly excludes consideration of the likely public health effectiveness of BAT-level controls for source

---

3/ Neither the statute nor the legislative history specifically addresses the role of risk assessment information in standard-setting or spells out the nature of the requirements to be applied under the "ample margin of safety" language for pollutants that may present health risks at any level of exposure. In the absence of specific statutory language, EPA's practice has been to rely on a technology-based approach in regulating these pollutants.

categories posing "significant" risks. At other points in its decision process, where EPA does consider risk assessment information, it does so in a way that imparts a large and inappropriate conservative bias to the ultimate regulatory decision.

In this paper we begin by considering the regulatory policy that results from the standard-setting approach used in EPA's proposed rules (Section B). We then discuss EPA's use of a BAT-approach and the possible modification of that approach described in EPA's proposed rule for limiting inorganic arsenic emissions from low arsenic feed copper smelters (Section C). Finally, we discuss the role of risk assessment information at other junctures in EPA's standard-setting process, and the relative weighting given to reductions in individual risk as opposed to population risks from exposure to these substances (Section D).

B. The Effectiveness of EPA's Regulatory Requirements

The objective of the Section 112 hazardous air pollutant standards is protection of public health, so it is important to assess the effectiveness of EPA's standard-setting decisions in terms of the likely public health gains. We have developed such information on the public health effectiveness of EPA's proposed BAT standards using available data for sources emitting radionuclides and inorganic arsenic. (See Table I.) In the

TABLE I

Costs and Cost-Effectivness of EPA's Proposed Rules for Radioactive and Toxic Substances

	Cost of Proposed Standard (Dollars in Millions)		Expected Change in Cancer Incidence (Cancers/Year)	Cancers Avoided Per Million Dollars of Expenditure	
	Capital	Annualized a/		Average for Sources Regulated	Range for Sources Regulated
Radionuclides					
DOE Facilities	25.0	4.2	0.006	0.001	b/
NRC-Licensed Facilities	0.0	0.0	0.0	-	c/
Uranium Mines	-	4.0	0.7	0.18	d/
Elemental Phosphorous	6.0	3.0	0.012	0.004	b/
Inorganic Arsenic					
High Arsenic Feed Copper Smelters	3.5	1.5	3.0	2.0	e/
Low Arsenic Feed Copper Smelters	35.0	9.5	0.09	0.01	0.14 to 0.001
Glass Manufacturing Plants	27.4	4.9	0.25	0.05	0.17 to 0.003
Total	96.9	27.1	4.06		

---

a/ Stream of annual costs, including interest and depreciation.

b/ Only two sources regulated; both sources have similar characteristics in terms of population exposed and the cost of meeting the proposed standard.

c/ Not applicable.

d/ No data for individual sources.

e/ Only one source regulated.

Source: U.S. Environmental Protection Agency.

case of EPA's proposed rule for sources emitting inorganic arsenic, for example, the public health gains per million dollars expenditure range from 2 expected cancers avoided per million dollars of expenditure for the high arsenic-feed copper smelter at Tacoma, Washington, to less than 0.001 expected cancer avoided per million dollars of expenditure for some of the other copper smelters and glass manufacturing plants regulated under the proposed rule. The effectiveness of EPA's proposed rules in terms of public health gains varies across individual plants by a factor of 2,000. To place in perspective an effectiveness of 0.001 expected cancer avoided per million dollars of expenditure, it would require an expenditure of one billion dollars to avoid a single expected case of cancer.

In fact, most of the public health gains projected for these rules result from the control of emissions at a distinct subset of these plants. Regulation of the remaining plants (or sites) yields relatively little in additional expected public health gains. In the case of the proposed rule for low arsenic-feed copper smelters, for example, regulation of the secondary emissions from converter operations at three smelters (ASARCO-El Paso, ASARCO-Hayden, and Kennecott-McGill) accounts for 88 percent of the total reduction in cancer incidence under EPA's proposed rule (covering both converter and matte and slag operations). Much of the cost of EPA's proposed standard (65 percent) is associated with the control of smelter operations contributing only 12 percent of the expected public health gains.

In the case of radionuclides as well, 97 percent of the public health gains can be achieved at forty percent of the cost by only regulating underground uranium mines.

As a result, an alternative regulatory strategy that emphasizes the effectiveness of further control can achieve most of the public health gains at substantially lower cost. For example, EPA estimates that its proposed standards for sources emitting these two hazardous pollutants would achieve an expected aggregate reduction in cancer incidence of 4.06 cancers per year at an aggregate cost of $27.1 million per year. An alternative regulatory strategy establishing the proposed BAT level of control only for those plants where the effectiveness of further control is relatively high could achieve an estimated reduction in cancer incidence of 3.92 cancers per year at an aggregate cost of $7.4 million per year. In other words, 96 percent of the expected health benefits of EPA's proposed rules could be achieved under this alternative strategy at only 27 percent of the expected costs. EPA's proposed standards requiring further control for the remaining plants (not regulated under this alternative strategy) would achieve an additional estimated reduction in cancer incidence of only 0.13 cancers per year at a cost of $19.7 million per year.

C. Reliance on BAT Approach for Standard-Setting

In setting standards for source categories posing a significant risk, EPA relies on a BAT approach that focuses on the application of "feasible" control technologies taking into account such factors as the "economic impacts" of meeting the required level of control. Although EPA does not provide criteria specifying what might constitute unreasonable economic effects, EPA in its BAT determination typically considers a variety of factors, including: 4/

- the technical feasibility of the proposed control requirements; and
- the economic effects of the proposed requirements, including the effects on industry profitability, product prices, and likely plant closures.

As a part of its BAT determination, EPA may also establish subcategories reflecting a variety of factors including differences in technology, age of plants, or economic characteristics.

The various environmental statutes envision BAT determination as a fairly straightforward "engineering problem" of identifying readily available control technologies that every well-operated

---

4/ In its proposed rule for source categories emitting inorganic arsenic, for example, EPA cites each of these factors in its decision not to regulate individual source categories. 48 FR 33112.

plant should have in place. In fact, it has become a much more complicated standard-setting process of identifying "feasible" control technologies, evaluating their effectiveness, and assessing the character of the burdens their required use places on society--that is, economic effects such as likely plant closures and price increases, energy consumption, or other adverse environmental effects.

As a part of this process, for example, EPA identifies source categories and subcategories as a way of differentiating the stringency of BAT control requirements across plants and obtaining more reasonable regulatory standards. Certainly, it would not be feasible (or sensible) to establish a single standard for, say, both copper smelters and glass manufacturing plants. As a result, EPA establishes standards for specific industry source categories and often uses a further subcategorization within specific industries as a way of tailoring its standards. In its proposed rule limiting inorganic arsenic emissions from various industrial sources, for example, EPA proposed a regulatory strategy involving a further categorization (and subcategorization) within specific industrial categories based on the "potential" of these facilities to emit inorganic arsenic. Thus, EPA proposed to establish separate categories for "high" and "low" arsenic-feed copper smelters. In addition, EPA discusses and requests comments on two alternative approaches that would establish subcategories based on population exposure or public health risk.

[illegible] requirements in terms of the likely public health gains in light of the costs of achieving further control. To illustrate this point, we first discuss EPA's BAT approach in setting proposed standards for sources emitting inorganic arsenic, and then consider the alternative approaches discussed by EPA for subcategorization using information on population exposure or public health risk.

1. EPA's BAT Determination in the Proposed Rule

In making its BAT determination, EPA uses the categorization (and subcategorization) of sources to differentiate the stringency of BAT-level control requirements across plants. In the case of copper smelters, for example, EPA proposes to establish two distinct source categories--"high feed arsenic" and "low feed arsenic" copper smelters--and proceeds with a separate determination of BAT-level control requirements for each of these source categories.

EPA is also proposing to establish what are in effect subcategories of plants within the low arsenic feed copper smelter and glass manufacturing source categories in order to differentiate the stringency of BAT-level controls within these source categories. In the case of control requirements for secondary emissions from converter operations, for example, EPA concluded that BAT required further control at the six copper smelters with a feed material arsenic content greater than 6.5 kilograms per hour. For the remaining eight smelters, EPA concluded that BAT does not require the control of these secondary emissions. 5/ Similarly, in setting BAT standards for secondary emissions from the matte and slag operations of these copper smelters and the furnace emissions from glass manufacturing plants, EPA concluded that the control cost for plants with a relatively low potential to emit was unreasonable in light of the small emission reduction achieved. As a result, EPA concluded that BAT required the control of secondary emissions from matte and slag operations at only four of the fourteen low arsenic feed copper smelters and the control of arsenic emissions from fourteen of nineteen glass furnaces.

In discussing these proposed regulatory cutoffs, EPA noted that its analysis did not provide a clear cutoff--a "knee" in the cost curve--at which the costs of control were clearly "unreasonable" in comparison with the likely emission reductions. 6/ Indeed, EPA's emissions and removal cost data for both the low arsenic feed copper smelters and glass manufacturing plants suggest a continuum with increasing removal costs as the potential emissions of these plants decline. (See Tables II and III.)

5/ 48 FR 33143.

6/ 48 FR 33143 and 33157.

Table II

Removal Costs for Secondary Inorganic Arsenic Emissions from the Operations of Low Feed Arsenic Copper Smelters

	Converter Operations		Matte and Slag Operations	
	Potential Arsenic Emissions (Mg/year)	Cost per Unit Emission Reduction ($/Mg As)	Potential Arsenic Emissions (Mg/year)	Cost per Unit Emission Reduction ($/Mg As)
ASARCO-El Paso	98.0	16,200	6.5	382,500
ASARCO-Hayden	58.5	16,400	13.8	-
Kennecott-McGill	45.9	64,800	4.5	65,900
Kennecott-Garfield	7.7	185,400	2.0	302,400 a/
Phelps Dodge-Morenci	6.9	302,900	0.9	642,500
Kennecott-Hayden	6.5	335,900 a/	0.9	321,300
Phelps Dodge-Douglas	4.3	710,800	0.6	1,469,000
Phelps Dodge-Ajo	2.6	679,100	0.6	494,300
Inspiration-Miami	1.7	1,777,000	0.8	372,900
Phelps Dodge-Hidalgo	1.2	1,586,000	0.2	1,512,000
Kennecott-Hurley	0.5	5,861,000	0.1	3,313,000
Tennessee Copper-Copperhill	0.7	2,130,000	0.09	3,671,000
Magma-San Manuel	0.5	8,842,000	0.09	6,425,000
White Pine	0.3	4,733,000	0.05	6,425,000

a/ Plants with potential arsenic emissions above this cutoff would be required to install controls under EPA's proposed rule.

Source: 48 FR 33143-33144.

Table III

Removal Costs for the Inorganic Arsenic Emissions from Glass Manufacturing Furnaces

Existing Furnaces Without Add-on Control Devices	Uncontrolled Arsenic Emissions (Mg/Year)	Cost per Unit Emission Reduction ($/Mg)
1	15.20	36,100
2	3.35	112,300
3	3.09	132,400
4	3.09	123,000
5	1.99	194,000
6	1.83	299,400
7	1.83	137,800
8	1.27	236,000
9	0.91	295,100
10	0.76	726,500
11	0.73	447,000
12	0.55	652,000
13	0.55	714,000
14	0.45	795,000 a/
15	0.12	1,200,000
16	0.04 b/	9,666,700
17	0.04 b/	9,666,700
18	0.04 b/	9,666,700
19	0.04 b/	9,666,700

---

a/ Plants with uncontrolled arsenic emissions above this cutoff would be required to install controls under EPA's proposed rule.

b/ These four furnaces are vented through a single stack.

Source: 48 FR 33157.

Although EPA cites cost-effectiveness as one of the major criteria used in setting BAT, 7/ there are important differences across source categories in the level of removal costs that EPA finds to be reasonable. Thus, the BAT removal costs for controlling secondary emissions at copper smelters generally fall below $400,000 per megagram of arsenic removed. 8/ In the case of glass manufacturing plants, however, EPA finds that removal costs up to $800,000 per megagram are "reasonable." 9/ As a result, we could not identify a clear set of criteria applied in a consistent fashion that differentiates those facilities subject to the proposed more stringent BAT requirements from the remaining plants.

7/ 48 FR 33116.

8/ The estimated removal costs of controlling secondary emissions for matte and slag operations at the ASARCO-El Paso plant are $382,000 per Mg removed; however, the proposed rule exempts these operations at two smelters with estimated removal costs of roughly $350,000 per Mg.

9/ Emission standards imposing removal costs on some plants in one source category double the maximum costs imposed on plants in another source category are unlikely to be cost-effective. In fact, EPA could achieve a more cost-effective outcome by using a removal cost ceiling of $500,000 per Mg arsenic removed. Under this cost-effectiveness cutoff, the secondary emissions from the matte and slag operations of these additional low arsenic feed copper smelters would be controlled at an additional cost (annualized) of $780,000; but, four glass manufacturing furnaces would no longer be required to control emissions at a cost savings of $1,500,000. This regulatory approach would achieve the same reduction in inorganic arsenic emissions as that proposed by EPA at a net cost savings of $700,000 per year. EPA did not consider public exposure in selecting its cutoff levels and this outcome is "cost-effective" only in terms of a reduction in emissions. As outlined below, an alternative decision process giving explicit consideration to public health gains might well result in a different regulatory outcome.

Because the purpose of these regulations is improved public health, it is difficult to know what would be a "cost-effective" or a "reasonable" removal cost without considering information on the public health effects of alternative control strategies. For example, an emphasis on adjusting a particular mix of regulatory requirements to yield more "cost-effective" reductions in arsenic emissions may not be the best way to improve public health protection because of the substantial differences in population densities in the vicinity of plants. In addition, of course, even a "cost-effective" emission reduction when appraised in terms of public health gains achieved may involve too much or too little control of these plants; this is because the initial level of control was determined without reference to levels of control that would be considered "reasonable."

2. Subcategorization by Population Exposure

EPA recognizes that its reliance on a BAT approach focuses on the "feasibility" of installing specific control technologies and that little consideration is given to the likely exposure and health risks associated with emissions from these plants. 10/ As EPA notes in its preamble, there are substantial variations across plants in terms of public exposure and health risk. As a result, EPA discusses two alternative ways of taking this information into consideration in setting standards for source

---

10/ 48 FR 33145.

categories posing "significant" risks. One alternative would be to subdivide source categories on the basis of population density before determining BAT. Within high population density areas (for illustrative purposes, EPA uses a population cutoff of 10,000 persons within 20 kilometers), BAT level controls would be more stringent than for plants within low population density areas. EPA's second alternative would subdivide sources into higher-risk, lower-risk categories by using risk assessment information for both individual risk and aggregate cancer incidence (see Table IV for the risk-exposure cutoffs used by EPA). Under this alternative, higher-risk facilities would be required to install BAT while lower-risk smelters would not be regulated.

We support EPA's effort to consider additional information on public exposure and health risk in setting standards. We think that consideration of this kind of information is essential to sound public health regulation. However, we are concerned about the way in which EPA proposes to use this information as a part of the standard-setting process. Under EPA's two alternative approaches, exposure and health risk information would be used to establish separate subcategories of sources, and EPA would then determine the level of control representing BAT for each "risk" subcategory. For example, EPA suggests that it might establish a lower feed rate cutoff--that is, a more stringent regulatory cutoff--for plants located in high density population areas.

Table IV

Risk and Exposure Cutoffs Under EPA's Alternative Approach

A. Population Density

If the Population Density within 20 km is Greater than 10,000	THEN	The Smelter Would be Classified "Higher Risk"

B. Risk/Health Effects Cutoffs

If the Maximum Individual Risk is Greater than:	AND	The Expected Annual Cancer Incidence is Greater than:	THEN	The Smelter Would be Classified "Higher Risk"
10^{-1}		0.0014		
10^{-2}		0.0014		
10^{-3}		0.0140		
10^{-4}		0.0140		
10^{-5}		0.1400		
10^{-6}		1.4000		

Source: 48 FR 33146-33147.

This would require some plants in high density areas to control emissions while plants with similar operating characteristics in low density areas would not be required to control their emissions further. Again, it is unclear what criteria EPA would rely upon in setting BAT standards for plants falling in one or the other subcategory. 11/ It appears, though, that EPA would continue to rely on a technology-based approach in determining the appropriate level of control within the "high" and "low" risk subcategories.

If EPA relies on technology-based criteria in making this decision, it is likely to require "too much" or "too little" control of individual plants. The problem arises because the use of "high" and "low" risk subcategories, as discussed by EPA, retains a formal separation of the consideration of public exposure and health risk information from the determination of the level of control constituting BAT. In our view, this information ought to be considered jointly by weighing both the public health gains and the costs of a further control of these plants. This approach would lead, we believe, to more sensible regulatory decisions than the several approaches outlined by EPA.

11/ In setting BAT requirements for copper smelters in high population density areas, EPA would require control of the secondary emissions from matte and slag operations at the Kennecott-Garfield plant at an estimated removal cost of $302,000 per Mg of arsenic removed; but, EPA would not require control of the smelter's secondary emissions from converter operations even though the estimated removal cost is only $185,000 per Mg. 48 FR 33143-33144.

The problems with each of the alternative approaches considered by EPA can be illustrated by considering the cost-effectiveness in terms of expected public health gains of the required further control for individual plants. Under EPA's proposed rule, the average cost of the expected reduction in population risk for the "low" arsenic copper smelters is roughly $100 million per cancer avoided and the cost-effectiveness of the required control for individual sources varies from $7 million per cancer avoided to $1.3 billion per cancer avoided. (See Tables V and VI.) The wide variation in the effectiveness of the control of these emissions occurs because of the variation across individual smelters in the amount of pollutant discharged to the air at current levels of operation, the size and location of the exposed population, and the costs of achieving further reductions in emissions.

Under the alternative approaches outlined by EPA, the average cost of the expected reduction in population risk is somewhat reduced and the range in cost-effectiveness across copper smelters is generally narrowed. (See Table VII.) However, the average cost of the expected reduction in population risk under these alternative approaches remains extremely large--the average cost is roughly $70 million per cancer avoided under the population cutoff approach and $85 million per cancer avoided under the risk-exposure cutoff approach. Risk-reduction investments in this range would go far beyond those customarily required by EPA and other public health agencies, and far beyond

TABLE V

Arsenic Emission Control Systems for Converter Operations

	Annualized Control Costs ($1000)	Cost Per Unit Emission Reduction ($/Mg As)	Change in Annual Incidence of Fatal Cancers (Cancers/year)	Cost Per Unit Reduction of Fatal Cancer ($/Cancer)
ASARCO - El Paso a/	307	16,200	0.043	7,000,000
ASARCO - Hayden a/	403	16,400	0.019	21,000,000
Kennecott - McGill a/	2,696	64,800	0.019	140,000,000
Kennecott - Garfield a/	1,300	185,400	0.0015	870,000,000
Phelps Dodge - Morenci a/	1,908	302,900	0.0027	710,000,000
Kennecott - Hayden a/	1,982	335,900	0.004	500,000,000
Phelps Dodge Douglas	2,943	710,800	0.003	980,000,000
Phelps Dodge Ajo	1,562	679,100	0.005	310,400,000
Inspiration - Miami	2,943	1,777,000	0.011	270,500,000
Phelps Dodge - Hidalgo	1,745	1,586,000	0.000001	b/
Tennessee - Copperhill	1,278	2,130,000	0.0015	850,000,000
Magma - San Manuel	3,979	8,842,000	0.00066	6,000,000,000
Kennecott - Hurley	2,296	5,861,000	0.0004	5,700,000,000
White Pine	1,278	4,733,000	0.0001	12,800,000,000

---

a/ Regulated under EPA's rule.

b/ Greater than a trillion dollars per cancer avoided.

Source: U.S. Environmental Protection Agency.

TABLE VI

Arsenic Emission Control Systems for Matte and Slag Operations

	Annualized Control Costs ($1000)	Cost Per Unit Emission Reduction ($/Mg As)	Change in Annual Incidence of Fatal Cancers (Cancers/year)	Cost Per Unit Reduction of Fatal Cancer ($/Cancer)
ASARCO - Hayden a/	0	-	-	-
ASARCO - El Paso a/	153	382,500	0.0008	190,000,000
Kennecott - McGill a/	257	65,900	0.0019	135,000,000
Kennecott - Garfield a/	514	302,400	0.0004	1,300,000,000
Phelps Dodge - Morenci	514	642,500	0.0003	1,700,000,000
Kennecott - Hayden	257	321,300	0.0005	510,000,000
Inspiration - Miami	261	372,900	0.0044	59,000,000
Phelps Dodge Ajo	257	494,300	0.0009	296,000,000
Phelps Dodge Douglas	514	1,469,000	0.000263	1,950,000,000
Phelps Dodge - Hidalgo	257	1,512,000	0.000000015	b/
Tennessee - Copperhill	257	3,671,000	0.000232	1,100,000,000
Margina - San Manuel	514	6,425,000	0.000117	4,400,000,000
Kennecott - Hurley	265	3,313,000	0.00007	3,800,000,000
White Pine	257	6,425,000	0.000015	17,000,000,000

---

a/ Regulated under EPA's proposed rule.

b/ Greater than a trillion dollars per cancer avoided.

Source: U.S. Environmental Protection Agency.

Table VII

Public Health Gains and Cost Under Alternative Regulatory Approaches

	Number of Regulated Smelters	Annualized Cost of Required Controls (dollars in million)	Reduction in Annual Incidence of Cancer (cancers/year)	Average Cost Per Cancer Avoided ($millions/cancer)	Range in Cost Per Cancer Avoided ($million/cancer)	
					Low	High
Converter-Operations:						
EPA's Proposed Rule	6	8.6	0.089	96.6	7.0	870.0
EPA's Alternative Population Cutoff	3	3.4	0.081	42.0	7.0	140.0
EPA's Alternative Risk/Exposure Cutoff	5	7.9	0.097	81.4	7.0	310.0
Matte and Slag Operations:						
EPA's Proposed Rule	4	0.92	0.003	298.0	7.0	1,300.0
EPA's Alternative Population Cutoff	5	1.2	0.0075	158.7	7.0	1,300.0
EPA's Alternative Risk/Exposure Cutoff	5	0.93	0.008	116.0	7.0	296.0

those customarily assumed by individuals in private decisions involving health risks. 12/ Moreover, cost-effectiveness under EPA's risk-exposure approach still ranges from $7.0 million to $312 million per cancer avoided, while EPA's population density approach does not reduce the variation in cost-effectiveness in the proposed rule at all--it continues to range from $7.0 million to $1.3 billion per cancer avoided.

As these examples illustrate, taking risk and population exposure into consideration by subcategorizing sources into high and low population or risk groups does not automatically yield a sensible result. Subcategorization of a source category on the basis of population exposure or public health risk may serve to narrow the range in the cost-effectiveness of control requirements; but a sensible result depends on the determination

---

12/ For example, these costs are substantially above current estimates of the willingness-to-pay for small reductions in the risk of death. These estimates yield a willingness-to-pay for a reduction in the aggregate risk of cancer incidence ranging from roughly $500 thousand to $7 million per death avoided. For a summary of this literature see: U.S. Environmental Protection Agency, Valuing Reductions in Risks: A Review of the Empirical Estimates, Washington, D.C., 1983; Martin J. Bailey, Measuring the Benefits of Life-Savings, Washington, D.C.: American Enterprise Institute, 1979.

of the level of control constituting BAT for each plant within a subcategory. 13/

D. Use of Risk Assessment Information in Standard-Setting

The use of risk assessment information is critical, in our view, to making reasonable regulatory judgments. As outlined above, ignoring information about public health risks at a critical juncture in the standard-setting process results in standards with costs per health risk reduction that vary widely across plants and across hazardous substances. In this section, we discuss the issue of risk assessment more generally and consider the use of risk information at other stages of the standard-setting process. We conclude with recommendations on the relative weighting to be given to reduction in individual risk as opposed to the population risks from exposure to hazardous air pollutants.

13/ The wide range in cost-effectiveness using high and low population subcategories results from EPA's determination that BAT requires the control of the secondary emissions from matte and slag operations at the Kennecott-Garfield smelter. We noted above that this BAT determination appeared to be inconsistent with EPA's determination that no further control of emissions from converter operations would be considered to be BAT at this smelter, even though control of these latter emissions would be more cost-effective. We are not certain, however, of the criteria EPA uses in arriving at its BAT determinations, and therefore cannot be certain EPA has been inconsistent in using these criteria.

1. EPA's Use of Risk Assessment Information

EPA offers the following rationale for its use (and nonuse) of risk assessment information at various stages in the standard-setting process. 14/

> The use of risk estimates generally has been confined to areas of broad comparisons, e.g., in selecting source categories to evaluate, and in assessing the incremental change in risk that results from application of various control options. The use of risk estimates in an absolute sense is avoided because of the many uncertainties of the estimates. These uncertainties are compounded as the focus is narrowed. In other words, in evaluating specific sources, as opposed to source categories, the uncertainties associated with the risk estimates increase dramatically.

Although EPA stresses the uncertainty associated with its risk information, it nevertheless uses this information both in its initial screening of source categories to determine whether they pose a significant public health risk and in its residual risk assessment. At the residual risk assessment stage, in particular, EPA relies heavily on risk assessment information by explicitly weighing the likely additional public health gains of going beyond BAT with the costs of a more stringent standard. The residual risk assessment step in the standard-setting process directly considers whether more stringent controls resulting in

---

14/ 48 FR 33116.

plant closures are warranted--the issue that appears, at least to outsiders, to be the major economic concern in EPA's decision process.

Since EPA uses risk information at this critical juncture in the decision process, it should use risk information at other stages as well. After all, the risk information is the best information available on the public health effects of alternative regulatory actions, which presumably is the issue of primary concern. Acting without such information in setting technology-based (BAT) standards is to risk imposing regulatory requirements arbitrarily, and expending scarce resources without any commensurate gains in public health.

There is, of course, some uncertainty associated with the risk assessment information, just as there is some uncertainty with EPA's cost estimates. 15/ We believe that the decision-making process should proceed on the basis of the best information available for both the public health gains and the economic costs. A choice can then be made among regulatory

---

15/ EPA uses conservative assumptions in developing its risk information. For example, the quantitative risk estimates developed by EPA for these three substances are based on a linear no-threshold model. EPA states that the resulting risk estimate "...represents a plausible upper-limit estimate in the sense that the risk is probably not higher than the calculated level and could be much lower." 48 FR 33114. However, EPA's quantitative risk assessment is generally based on a specific health effect, e.g., leukemia, without considering other likely health effects. To the extent that the substance causes other health effects, these ought to be considered as well in assessing the likely public health gains from regulation.

alternatives by explicitly considering both the best estimates of the likely effects of these alternatives and the uncertainties associated with these estimates.

This approach is superior to a conservative approach that relies on "worst case" estimates of health and economic effects, because it provides a clear statement of the likely effects and uncertainties of the available regulatory alternatives for those making the ultimate policy decisions. Policy decisions based solely on "worst case" assumptions about health risks yield "margins of safety" of unknown magnitude--making it impossible to assess the likely gains of selecting successively more stringent regulatory alternatives.

In addition, the direct weighing of the likely public health gains with the costs in assessing alternatives is superior to obscuring the likely effects of regulation by neglecting information at important steps in the standard-setting process. 16/ As

---

16/ This emphasis on the use of "best" estimates accompanied by explanations of surrounding uncertainties is an extension of the recent National Academy of Sciences report recommending a clear "...distinction between assessment of risks and consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies." National Academy of Sciences, Committee on the Institutional Means for Assessment of Risks to Public Health, Risk Assessment in the Federal Government: Managing the Process, NAS-NRC, March 1983. In our view, this distinction should be maintained in the analysis of alternative standards. Margin of safety considerations should be deferred to a later stage in the decision process where the uncertainties involved can be explicitly considered in designing a regulatory strategy.

we have noted above, EPA's present BAT approach imparts a conservative bias to the standard-setting process because it implicitly assumes that the benefits of a BAT level of control exceed the costs without regard for the estimated public health gains, however negligible. In many cases, however, this implicit assumption appears to be wrong. An alternative approach that considered both the public health gains and costs would yield a more effective use of resources for public health (or other) purposes.

2. Designation of a Significant Risk

At the initial stage in its standard-setting process, EPA determines whether the emissions from a source category pose a "significant" public health risk. In doing so, EPA considers whether the substance emitted is a human carcinogen and whether individuals or larger populations are significantly exposed to the substance. However, EPA reports that it has not used a "numerical target level" of significant exposures because of the uncertainties associated with its risk estimates. 17/

There is indeed no pattern in EPA's proposed rules that suggests the use of a systematic cutoff in regulating source categories emitting hazardous pollutants. In its proposed rules for source categories emitting radionuclides and inorganic

---

17/ 48 FR 33116.

arsenic, EPA proposed standards for seven source categories. In addition, EPA specifically considered and decided not to propose standards for ten other source categories it had identified at the time of listing these pollutants. 18/ EPA reached its decision on whether to propose standards for these source categories only after making a BAT determination and a residual risk assessment for each source category.

By deferring to a later stage in the standard-setting process the decision whether to propose standards, EPA was able to consider a variety of other factors, including the potential for further reductions in emissions (taking into account current regulatory requirements), the likely reduction in public health risk, and the costs and other economic effects of requiring more stringent control of these source categories. The deferral of a decision whether to propose a standard until a later stage in the standard-setting process represents, in our view, a tacit recognition that an informed decision on the need for further regulation can be reached only after weighing the likely public health gains with the costs and other economic effects (e.g., plant closures) of further regulation.

In general, this appears to be a good way to proceed. It is difficult to establish *a priori* a cutoff point that

---

18/ EPA has taken no action for one source category--fossil fuel-fired combustion--identified in the listing of inorganic arsenic as a hazardous pollutant.

distinguishes "significant" public health risks from "acceptable" risks. The health risks posed by the various source categories identified by EPA as emitting inorganic arsenic and radionuclides illustrate the problem. There is no pronounced gap or clustering in the risks posed by the various source categories identified by EPA--rather, there appears to be a continuum from the highest risk sources to those sources posing lower risks. (See Figure 1.)

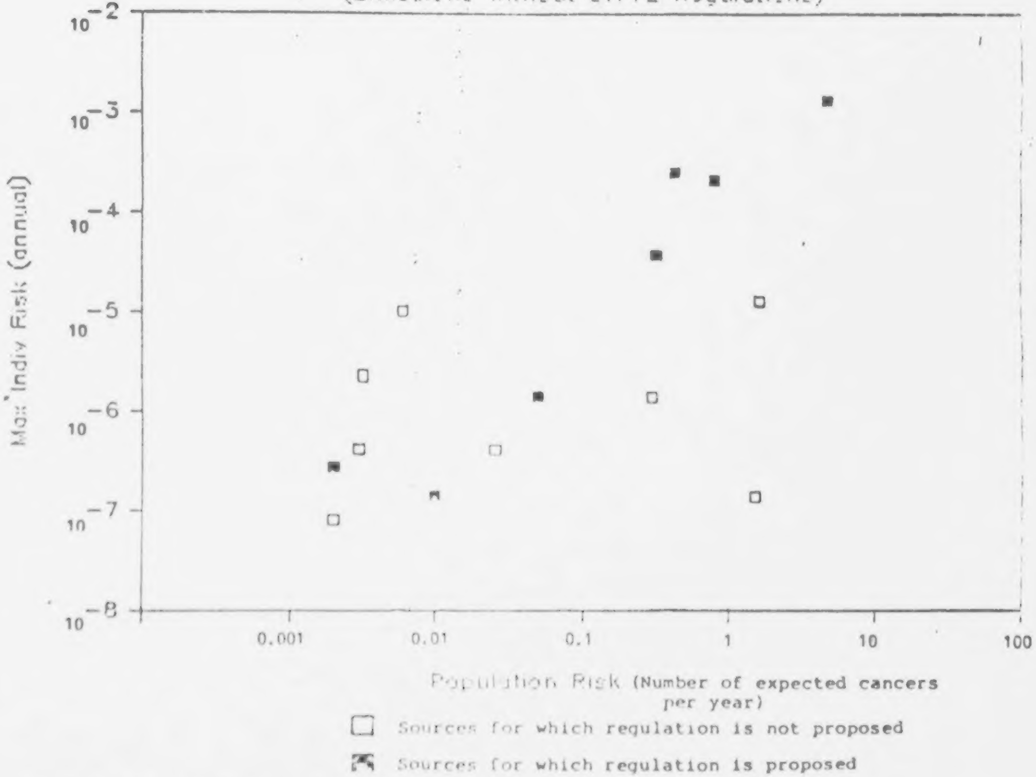
We believe it is difficult to identify a de minimis level of public health risk without considering other factors influencing the likely public health gains of further regulation. However, EPA may find that there are administrative advantages to establishing a de minimis risk level. This would allow EPA to direct its attention toward those source categories posing the greatest public health risks. In addition, if EPA finds that it is precluded by statute from directly weighing the likely public health gains with the costs of regulation, an explicit de minimis threshold for public health risk at an initial stage in the standard-setting process could serve to screen out a number of cases where regulation would achieve only negligible gains in public health.

We encourage EPA to review the role of this initial stage in its standard-setting process. If EPA decides that an initial step of designating source categories posing significant public health risks serves a useful administrative role, we believe EPA

Figure 1

Individual and Population Risks

(Emissions Without S.112 Regulations)



Source: U.S. Environmental Protection Agency.

should establish explicit criteria identifying levels of public health risk warranting further regulatory consideration. If EPA should do so, we would suggest the following as de minimis levels of public health risk: EPA would consider further regulatory action for a source category if the aggregate annual cancer incidence at current emission levels for the source category is one likely cancer or more per year. In addition, EPA might want to consider regulatory action where annual risks to the most exposed individual are relatively high--for example, on the order of one in ten thousand or more.

Our suggested cutoff for aggregate population risk is based on the following observation: where the annual cancer incidence at current emission levels is less than one cancer per year, any additional regulatory requirements would likely impose costs of several million dollars per year while only negligible public health gains would be achieved. Our suggested cutoff for individual risk is based on our argument (outlined below) that annual risks to the most exposed individual that are smaller than other risks generally encountered in the course of daily life need not be considered independently of aggregate population risk.

3. The Measure of Individual Risk

In its preamble discussion, EPA outlines its concern for the individual risks to the most exposed members of the population and requests comments on the best way to consider individual risk in its decision process. 19/ We believe that annual individual risk is a better measure than EPA's measure of "maximum individual lifetime" risk. "Maximum individual lifetime" risk incorporates several important assumptions that overstate actual individual risks. 20/

First, maximum lifetime estimates of individual risk assume that the individual receives the maximum exposure to the substance--in effect, at the fenceline of the "worst" facility--continuously for the full 70 years. The population in the United States is highly mobile, however, and it is extremely unlikely that any individual would remain in a single location for a lifetime. In addition, many of these facilities have a limited life and are unlikely to operate for an additional 70 years. Second, a maximum individual lifetime risk estimate incorrectly assumes that the last year of exposure (the seventieth year) contributes as much to the individual's health risk as earlier years of exposure; in general, there is a long latency period between exposure and the onset of cancer.

For these reasons, annual risk to the most exposed person is a truer measure of maximum individual risk than EPA's measure of

---

19/ 48 FR 33116.

20/ This conservatism in the risk estimate is independent of the extent to which EPA has adopted conservative assumptions in its risk assessment.

"maximum individual lifetime" risk. The "maximum individual lifetime" risk estimate may convey some additional information as a "worst case" estimate, but in such cases it should be clearly treated as such.

4. Individual Risks Versus Population Risks

EPA has not yet decided what weighting to give in the standard-setting process to the estimated risk for the most exposed individual (or the more exposed individuals) vis-a-vis the estimated aggregate population risk. The issue is an important one because many of the facilities likely to be regulated under Section 112 are located at a distance from population centers. Although these facilities may pose some health risk to a limited population in the immediate vicinity, they pose only a relatively small aggregate population risk. As explained below, a decision to give extra weighting in the standard-setting process to individual risk for the most exposed members of the population would likely result in a more extensive regulatory intervention without commensurate public health gains.

EPA typically develops two measures of public health risk as a part of its standard-setting approach: the maximum individual lifetime risk and the population risk. EPA's estimate of maximum individual risk, as noted above, is the cumulative risk to the most exposed individual over a lifetime (70 years) of continuous exposure, and overstates the likely actual risk to the most exposed individual. 21/ Population risk is the aggregate of the individual statistical risks for the total exposed population--that is, the expected annual incidence of death for the exposed population due to the environmental hazard under consideration.

Population risk is, of course, the more comprehensive measure; we believe that in most cases it is also the better measure for purposes of establishing general public health standards such as hazardous air pollution controls. By definition, the aggregation of all individual risks in calculating the annual incidence of cancer for an exposed population provides the best estimate of the total public health gains to be expected from a regulatory standard. Risk management decisions should be based upon such best estimates of the likely effects of alternative standards. Particularly where risk information is uncertain and incomplete, basing each individual regulatory decision on population risk will tend to produce the greatest public benefits from the resources claimed by a succession of such regulations.

21/ In addition, where EPA applies this measure for a source category as a whole, the measure represents the maximum individual risk associated with the worst plant or facility in the source category. For many of the other facilities in the source category, maximum individual risk is often one to three orders of magnitude lower.

In our view, going beyond population risk to give additional weight to the (annual) risk to the most exposed individual is appropriate only where individual risk is greater than other risks routinely encountered in daily life. We do not know how frequently this might occur in the case of environmental regulation at the federal level, but it is not the case for many Section 112 rules. As shown in Table VIII, even those individuals who are *most* exposed to these environmental hazards face health risks that are *lower* than the *average* annual risk of death from an automobile accident (two in ten thousand), an occupational accident (one in ten thousand), a household accident (one in ten thousand), or a homicide (one in ten thousand). In circumstances such as this, regulations need not entail *relatively* greater risk-reduction investments for the most exposed individuals than EPA would otherwise require based upon the risks faced by the exposed population as a whole.

In the range from one in ten thousand to one in a million, the empirical evidence indicates there is little change in the valuation of small risk reductions with respect to the level of risk. 22/ This suggests that population risk gives an accurate weighting to the risks faced by those who are relatively more exposed as compared to those who are less exposed. Much of this

---

22/ Viscusi, W.K., *Risk by Choice: Regulating Health and Safety in the Workplace*, Cambridge, Mass.: Harvard University Press (1983), pp. 102-113. This is one of the studies reviewed in the literature surveys cited in footnote 12 above.

Table VIII

EPA's Estimate of Annual Cancer Risks for the Most Exposed Individual at Current Emission Levels [a]

Source Categories	Annual Risk to the Most Exposed Person [b]
High Arsenic Feed Copper Smelters	13.0×10^{-4}
Low Arsenic Feed Copper Smelters	2.4×10^{-4}
AVERAGE ANNUAL RISK OF DEATH DUE TO AUTOMOBILE ACCIDENTS	2.4×10^{-4}
Underground Uranium Mines	2.0×10^{-4}
AVERAGE ANNUAL RISK OF DEATH DUE TO WORKPLACE ACCIDENTS	1.3×10^{-4}
AVERAGE ANNUAL RISK OF DEATH DUE TO HOMICIDE	1.0×10^{-4}
AVERAGE ANNUAL RISK OF DEATH DUE TO ACCIDENTS IN THE HOME	1.0×10^{-4}
Glass Manufacturing Plants	0.35×10^{-4}
ESTIMATED ANNUAL RISK OF DEATH DUE TO NATURAL BACKGROUND RADIATION	0.20×10^{-4}
DOE Facilities	0.03×10^{-4}
Elemental Phosphorus	0.01×10^{-4}
NRC-Licensed Facilities	0.003×10^{-4}

a/ Source categories for which EPA has proposed additional control requirements.

b/ Midpoint in the range of EPA's estimate of risk to the most exposed individual; the range in EPA's risk estimate is based on the ninety-five percent confidence interval.

Sources: National Safety Council
U.S. Environmental Protection Agency
U.S. Department of Health and Human Services

evidence is based on studies of risk behavior in labor markets (reflecting the tradeoffs between worker salaries and workplace safety); there are also a few pertinent studies of consumer behavior yielding similar estimates of willingness-to-pay for small reductions in risk. 23/

The maximum individual risks for many of the source categories subject to these proposed regulations are less than the average annual level of risk considered in the cited studies. In referring to the evidence from the labor market studies, for example, we are making comparisons to a setting where the magnitude of risk exposure--roughly one in ten thousand--frequently exceeds that calculated by EPA for the most exposed individual in the environmental setting. In cases where the risk exposure in the environmental setting is substantially greater than the average level of risk considered in the cited studies, however, such a comparison would likely be invalid and

---

23/ These estimates provide a direct way of weighting individual risk in estimating population exposure. The available studies indicate a willingness to pay for a small reduction in risk ranging from $0.50 to $5.00 for a reduction in risk of one chance in a million per year. For example, these estimates indicate the willingness to pay for an annual reduction in risk of one chance in a million would range from $500,000 to $5,000,000 for a population of one million. If regulatory action yielded a reduction in risk of one in ten thousand for a population of 10,000 living near the regulated facility and a reduction in risk of one in a million for a larger population (of 990,000) located at greater distance from the facility, the willingness-to-pay for the resulting risk reduction would range from $995,000 to $9,950,000. See U.S. Environmental Protection Agency, Valuing Reductions in Risks, op. cit.

it might well be appropriate to give extra weighting in the decision process to individual health risks.

It may be argued that these studies are irrelevant to environmental exposures because the risk exposures involved in the studies were incurred "voluntarily," while environmental exposures are "involuntary". We think, though, that this argument overstates what are in effect relatively small differences across various types of risk exposure. For example, there is also an element of "involuntariness" associated with occupational exposures to risk--a factor emphasized by advocates of government regulation in the workplace. At the same time, there is an element of volition for the most exposed individual in accepting or avoiding the health risks from environmental exposures; because the level of exposure to these pollutants is highly location specific, the most exposed individuals can generally dramatically reduce their risks by slightly increasing the distance from the facility.

A more important point is that the labor market studies contain evidence on the effect of differences in the degree of volition on estimates of the willingness to pay to achieve small reductions in risk. For example, Viscusi has examined in a recent study the effect of differences in risk averseness across the workforce on the willingness-to-pay estimates. 24/ To do this, he estimated willingness to pay to avoid risk within

---

24/ See Viscusi, cited in footnote 22.

each quartile of risk averseness. Viscusi reports that the least risk averse quartile (i.e., the most willing to accept additional risk) of the workforce has a willingness to pay for a reduction in risk that is roughly one-half that for the remaining workforce. Further, he reports that for the more risk averse individuals (in the remaining three quartiles) there is very little variation from quartile to quartile in willingness to pay for small reductions in risk. Because there is less volition associated with job choice for the remaining three quartiles, 25/ and the willingness-to-pay estimates are almost the same (asymptotic) across these quartiles, Viscusi argues that the willingness-to-pay estimates for this more risk averse part of the population constitutes a "best" estimate of the willingness to pay for a small reduction in involuntary risk for the general population.

Finally, the willingness-to-pay estimates from the labor market studies involve a small reduction in the risk of immediate death. But reduced environmental exposure to a carcinogen, for example, yields a small reduction in the statistical probability of death at some time in the future (twenty or more years). There is reason to believe that the willingness to pay to reduce the risk of immediate death is greater than the willingness to pay to reduce the risk of contracting cancer at

---

25/ There is clearly a greater degree of volition involving such higher-risk occupational choices as deep sea diver or structural steel worker than in choosing the more routine occupations comprising the least risky occupational groupings.

some distant point in the future. Because the adverse health effects are delayed, the loss in years of useful life associated with contracting cancer at some point in the future is substantially smaller than the loss resulting from an immediate accidental death. In addition, of course, the adverse health effects of contracting cancer are deferred and time preference considerations alone reduce the willingness to pay. 26/

This evidence suggests that, over a broad range of environmental exposures where health risks are roughly comparable to other risks encountered in daily life, EPA need not give an additional weighting to any individual risks--maximum individual risks will be accounted for, as they are included in population risk estimates. Only in cases where the annual risks to individuals are exceptional--that is, substantially greater than the other risks of daily life--is there good reason to weight more heavily individual risk to the most exposed individual.

E. Summary

Greater attention to risk reduction in relation to control costs would substantially improve EPA's process of setting emissions standards for hazardous air pollutants. In particular, changing EPA's current practice of not considering risk

---

26/ For example, the present worth of a benefit delayed for twenty years is roughly half the current value at a real discount rate of three percent and it is roughly one tenth the current value at a real discount rate of ten percent.

information in setting "Best Available Technology" standards could produce major improvements in regulatory policy, and would be a logical extension of EPA's current use of risk information at other stages of the standard-setting process.

Under the current practice of using risk information only for limited purposes, the likely public health gains per dollar of expenditure resulting from recent EPA regulatory proposals could vary across sources by a factor of more than 2000. The expected reduction in cancer incidence ranges from less than 0.001 to 2.000 expected cases avoided per million dollars of compliance expenditures. At some plants, EPA expects compliance with its proposed standards to yield exceedingly small public health gains. Increased emphasis on likely reduction in exposure and health risks would lessen such extreme variation and improve EPA standards. This paper has discussed alternative regulatory strategies that could achieve most of EPA's intended public health gains at one-third of the cost or less.

The paper has made several other suggestions concerning the use of risk and cost data that are intended to strengthen the EPA regulatory process.

* * *

March 15, 1984

THE REGULATION OF NEW CHEMICALS UNDER THE TOXIC SUBSTANCES CONTROL ACT

SUMMARY

EPA's implementation of the Toxic Substances Control Act has placed an inordinate emphasis on the regulation of chemicals introduced since 1979. While EPA is obligated to review new chemicals before they are manufactured, it also has ample authority to regulate existing chemicals. Yet the agency has:

- devoted a disproportionate share of resources to reviewing and regulating new chemicals;
- sought to hold the risks associated with new chemicals to unreasonably low levels--possibly increasing overall public risk in some cases;
- proposed to expand the new chemical review program to areas not covered by the statute, such as export chemicals and biotechnology products;
- declined to develop usable exemptions from the new chemical review program for low-risk categories of chemicals.

The overall effect of EPA's implementation decisions is to convert the new chemical review program into more of a licensing program for chemicals, with possibly serious adverse effects on innovation. The program does not appear to be cost-effective as currently implemented. This paper discusses these issues and makes several suggestions for introducing more balance into the program.

BACKGROUND: THE TOXIC SUBSTANCES CONTROL ACT

The Toxic Substances Control Act of 1976 (TSCA) provides EPA with broad authority to regulate chemical substances in the environment, in the workplace, and in commercial products. TSCA's domain, unlike that of other health and safety statutes, is nearly unbounded. EPA may use it to regulate air, water, or land pollution; occupational hazards; consumer products; or any other source of potential risk to health or the environment. The risk need only be associated with some substance that is used in (or is a byproduct of) commerce. The Act exempts tobacco, nuclear materials, pesticides, foods, drugs, and cosmetics; otherwise virtually everything, natural or manmade, toxic or nontoxic, is covered--only the status of living organisms is in dispute.

The breadth of TSCA's reach reflects Congress' desire to "fill in the gaps" not covered by previous statutes. Indeed, various provisions of TSCA require the EPA Administrator to give priority to other laws, whether administered by him or by another agency, before deciding to use TSCA to control risks.1/ Few laws, however, confer as much authority as TSCA. Under Section 8, EPA has compiled an inventory of all chemical substances in commerce (currently about 60,000), and can require *reporting and recordkeeping* of any manufacturer or processor. Under Section 4, EPA can require *testing* by a manufacturer of any substance to determine whether it presents a risk. Under Section 6, EPA can *control* risks associated with a substance by:

- prohibiting or limiting manufacture, processing, or distribution, or ordering specific quality control procedures;
- prohibiting or limiting a particular use or regulating the manner or method of use;
- prohibiting or regulating any manner or method of disposal;
- requiring labels, warnings, or instructions to accompany the substance or any article containing it; or
- ordering a recall by the manufacturer.2/

In addition to the general authorities above, TSCA gives EPA a chance to *review new chemicals* prior to their introduction in commerce. Section 5 of TSCA requires any manufacturer (or importer) of a new chemical substance to notify EPA ninety days before manufacture begins. This premanufacture notification ("PMN") provides EPA an opportunity to evaluate chemicals before adding them to the inventory of commercial products. Once it is manufactured, a new chemical continues to be subject to all the authorities outlined above, like the 60,000 chemicals already listed on the inventory. During the ninety-day premanufacture review, however, EPA may impose essentially the same restrictions or testing requirements by administrative order.3/ This eliminates the need for a rulemaking, and allows EPA to act before manufacture begins. About 1,000 PMN notices are submitted each year.

1/ See TSCA Sections 6(c) and 9(a) and (b).

2/ See TSCA Section 6(a) and (b) for a more complete list. Also, Section 7 authorizes the seizure of chemicals, mixtures, or articles if the risk is judged serious and imminent.

3/ See TSCA Section 5(e) and (f). EPA may extend the 90-day review period, but not to more than a total of 180 days.

Congress recognized the potential of the PMN program to discourage innovation. For this reason, TSCA includes exemptions from the PMN requirement. Chemicals used only in research and development are exempt entirely; those undergoing test marketing may be exempted by application to EPA. Finally, EPA is authorized to exempt from Section 5 any category of chemicals that is found not to present an unreasonable risk.

IMPLEMENTATION: THE NEW CHEMICAL BIAS

Priorities

The implementation of TSCA mostly involves setting priorities for attention in the vast universe of chemicals and potential risks, and then making the difficult balancing judgments about which tests and which restrictions are worthwhile. So far, EPA has given the highest priority to reviewing new chemicals, and has apparently sought to limit risks associated with new chemicals to near zero.

Half of the staff and more than a third of the budget for implementing TSCA are devoted to the new chemical review program. If one could assume that the resources devoted to reviewing existing chemicals were as productive as those reviewing new chemicals (i.e., 1000 reviews per year), then a 50-50 split would imply a permanent 60-year lag in the review of existing chemicals. In actuality, the risks and regulatory problems associated with existing chemicals are far greater, and the staff has only been able to review, very roughly, six per year. This rate implies a 10,000 year lag in reviewing existing chemicals, growing by 150 years with each year that passes. While there is no statutory mandate to review systematically all existing chemicals, it seems certain that a reordering of priorities would be a better way to pursue statutory goals.

The tendency to focus on new risks, instead of old ones, is a common feature of health and safety regulation. It is a tempting strategy because it allows the regulator to avoid confronting established producer and consumer interests. However, it may bear little relationship to the relative magnitude of risks. In the case of chemicals, the new risks do not seem to be any different in character than the old--only smaller, since new products are not yet, and may never be, produced in large quantities or multiple locations.

Yet in the five years since the PMN program began 178 new chemicals have been subject to regulatory controls, compared to only four existing chemicals.4/

4/ The new chemicals include those subject to 5(e) Orders and Consent Orders, and 5(f) Orders, through January 1984. Withdrawals in response to agency concerns and PMN reviews
(Footnote continued)

Federal Licensing for New Chemicals?

As envisioned by the statute, the PMN program falls far short of a government "licensing" program such as applies to drugs and pesticides. Licensing for chemicals was debated in three congresses, and was rejected in favor of the PMN approach. The chief differences are:

Licensing for Drugs and Pesticides	Premanufacture Notification for Chemicals
May not be marketed without express prior approval by the government, which may take years to obtain.	Unless EPA acts to stop it, manufacture may begin 90 days after notice is given.
Manufacturers must prove, with test data, both efficacy and safety before marketing a product.	No test data are generally required, and the burden of proof is on the government if it wishes to regulate.
Approved for specific uses only and labeled accordingly--new uses, or new manufacturers, require new approvals.	Once a chemical enters commerce, it may be made by anyone and used for anything; the initial intended use has no binding effect.
The government may rescind its approval at any time.	Once PMN review is complete, it may not be reopened. The "new" chemical becomes "existing," and future controls must be imposed by rulemaking.

TSCA is due for reauthorization, and Congressman Florio is seeking amendments which would make the PMN program for new chemicals more like a licensing program. Prospects for passage are slim, but legislative action may be moot. Administrative steps taken or planned by EPA are gradually having the same effect. Despite Congress' decision not to impose licensing on new chemicals, the differences between simple notification and full-blown government licensing have begun to erode. This results from the dynamics of producer and EPA incentives, especially during the PMN process.

The first manufacturer of a new chemical does not yet have a

4/ (continued)
suspended indefinitely have not been counted. The four existing chemicals are polychlorinated biphenyls (PCBs), chlorofluorocarbons, asbestos, and dioxin.

strong commercial interest in it, and is rarely in a position to spend a lot of time and money overcoming regulatory barriers that may keep it from reaching the marketplace. Faced with agency demands, he has little choice but to cooperate or withdraw. Thus, in practice, TSCA's deadlines and burden-of-proof provisions do not assure that PMN review will be the straightforward process it was intended to be.

1) Need for prior approval: The 90-day PMN deadline (extendable to no more than a total of 180 days) is often further extended "voluntarily" by the manufacturer. Threatened with an adverse action by the agency, the manufacturer is encouraged to "stop the clock" until the agency is satisfied, or to withdraw the PMN completely.

2) Burden of proof: During PMN review, EPA can order testing of a chemical that "may present an unreasonable risk"[5] and can require controls on the chemical pending receipt of the data. Challenging such a vague finding in court probably would require performing the same tests the agency is seeking. EPA uses "worst case" assumptions and "safety factors" in making its risk findings, so that the burden of proof is effectively shifted to the manufacturer. That is, if EPA has any doubts about a chemical's safety, it is regulated unless and until the manufacturer performs tests that alleviate the agency's concerns.

3) Specific use restrictions: If EPA determines that a "significant new use" of an existing chemical may present an unreasonable risk, it may issue a rule requiring PMN review before that use occurs. The agency has not, in fact, applied this provision to any existing chemicals; instead it has repeatedly applied it to new chemicals so that they will have to go through multiple PMN reviews as they find their way into different uses.

4) Withdrawal of approval: After successful PMN review a new chemical may be placed on the inventory of existing chemicals. Its ordeal is not over, however. EPA has announced that it will draw a distinction between pre-1979 and post-1979 chemicals. As part of a "follow-up" program, newer chemicals will be monitored more closely and regulated more strictly than older ones, even when the newer ones are much less hazardous.

All of these steps tend to move premanufacture notification in the direction of new chemical licensing.

---

[5] Congressman Florio's proposed amendment would eliminate even this finding. It would also require that some testing be done in all cases.

The "Follow-up" Program: New vs. Old

One of the most troubling features of EPA's new chemical strategy is the so-called "follow-up" program. Under this program, the TSCA authorities that apply to all chemicals on the inventory--reporting and recordkeeping (Sec. 8), testing (Sec. 4), new use reviews (Sec. 5), and controls (Sec. 6)--will be applied preferentially to chemicals introduced in 1979 and later years. In addition to the PMN hurdle, these new chemicals will be subject to a follow-up program that may involve repeated reporting to EPA and continual uncertainty about the likelihood of expensive or prohibitive regulatory action.

Nothing in the Act suggests that a double standard should be applied to new and old chemicals.6/ Among existing chemicals, considerations of "unreasonable risk" might lead one to set regulatory priorities according to net benefit or relative risk; instead EPA is setting priorities based on vintage. The agency gives three reasons for treating recent chemicals more strictly than older ones. The first is illuminating:

> "PMN chemicals are in a fundamental sense different from chemicals on the Initial Inventory. Unlike chemicals on the Initial Inventory, they have been subject to EPA review. If a new chemical that has been through PMN review becomes the next PCB or vinyl chloride, this will generally be recognized as a failure of the PMN program."7/

Avoiding blame is an understandable concern, but not one that can be justified by a legitimate public objective. The agency ought to target those risks that pose the greatest threat to the public, not those that pose the greatest threat to the agency's reputation.

The second reason given is the impossibility of forseeing all future risks at the time a PMN is evaluated, necessitating a follow-up to control future risks. The reveals a misapprehension of the function of the PMN program. It is intended to supplement, not substitute for, the existing chemicals program. After a new chemical enters commerce it is subject to all the other authorities of TSCA, and the PMN reviewers should not be expected to anticipate and remedy all possible future risks. It

---

6/ Indeed, the Act appears to prohibit a double standard. Section 26(c)(2)(A) authorizes the Administrator to define categories of chemicals to be regulated as a group, but prohibits him from defining a category "grouped together solely on the basis of their being new chemical substances."

7/ Priorities for OTS Operation ("The 100 Day Report"), Environmental Protection Agency, January 1982, p. IIIA-3.

is also true that the future risks associated with existing chemicals are not completely forseeable. The follow-up program and the existing chemicals program should be integrated: whatever "follow-up" activity is directed at post-1979 chemicals should be essentially the same as the risk-identification activity for pre-1979 chemicals.

The third reason given for distinguishing pre- and post-1979 chemicals is the lower cost of regulating a chemical or a new use of a chemical before capital is committed to its production and use. This makes sense, and there is some basis for it in the legislative history of the Act. However, the degree of cost-difference has been exaggerated. The regulation of new chemicals often involves fewer real-resource costs, but more opportunity costs. Moreover, the follow-up program does not seem to be designed to achieve cost-savings.

"Unreasonable Risk"

TSCA does not specify which chemicals are to be regulated, or when, or how.8/ Unlike many regulatory statutes, it does not set forth absolute goals, such as "zero risk" or "safe workplace" or "best available technology." Rather, TSCA grants the EPA Administrator wide discretion in using its authorities. Throughout the Act, regulatory action is governed by findings of unreasonable risk: that a chemical may present unreasonable risk is generally sufficient to require testing; that it does present an unreasonable risk is the predicate for imposing controls.

The Act contains no definition of unreasonable risk, and sets no uniform threshold. Rather, the meaning of the term varies with the context, depending not only on the degree of risk but also on the action contemplated. The legislative history makes clear that the evaluation of unreasonable risk is to involve a balancing of the risks and benefits of any action contemplated. With respect to existing chemicals, EPA has stated its policy towards risk as follows:

"The Office of Toxic Substances will interpret

8/ The sole exception is polychlorinated biphenyls (PCBs), which are not discussed in this paper. In the course of the House floor debate on whether to mention PCBs in the Act, Mr. Eckhardt remarked:

> "Why should we, in enacting this act, move specifically to deal with PCBs and not PBBs? We are not attempting to . . . deal with vinyl chlorides by preventing their entry into the market. Nor are we attempting to regulate OMBs, a pernicious and persistent toxin that gets in the legislative environment."
> (Congressional Record, Aug. 23, 1976, p. H8830)

> 'unreasonable risk' under TSCA to mean a situation in which a judgment is made that the probability and magnitude of harm to society of the use of a chemical are likely to outweigh the benefits."9/

With respect to new chemicals, very little data is available about both risks and benefits, so this balancing can be difficult. Even the decision to resolve doubt through testing is not easy, since the relevant tests are often quite expensive. Judgments must be made that are necessarily uncertain. In practice, it appears that the evaluation of new chemicals has not involved a balancing of risks and benefits. Decisions on new chemicals seem to be driven instead by a desire to prevent risks altogether.

In reviewing new chemicals, EPA has used an extremely strict yardstick of risk. Toxicity is frequently determined by analogy to other chemicals that have been tested, and the reviewed chemical may be assumed to be more toxic in humans, by a "safety factor" of 100 or more, than its analogues have been found to be in animals. In addition, exposure is determined using worst-case assumptions. The uncertainty associated with new chemicals is so great that this "conservative" approach to risk assessment can show several orders of magnitude more risk than a best scientific estimate might predict.

In contrast, the benefits associated with new chemicals are not correspondingly inflated. No optimism is built into the benefits to balance the pessimism inherent in the risk assessment. For example, only a hint of indirect evidence is sufficient to persuade the agency to treat a new synthetic fuel as a carcinogen, and to assume that exposure will be widespread. Yet it is not likely to assume that the product will reduce the poverty or unemployment rate, the trade deficit, or acid rain.

Although the agency may attempt to balance risks and benefits, often it appears to seek to control any possible (non-carcinogenic) risks associated with a chemical to the level of "no observable effects." The combination of a conservative risk assessment based on indirect evidence and a no-observable-effects objective creates a strict standard of review--one that could easily exclude risks that would properly be regarded as reasonable.

An examination of the actions EPA has taken with respect to new chemicals does not reveal that human health or the environment are being made dramatically safer. Most actions relate to occupational exposures to possible carcinogens, and rarely is the potential risk a major one. The Regulatory Impact Analysis of

---

9/ Priorities for OTS Operation ("The 100 Day Report"), Environmental Protection Agency, January 1982, p. IV-7.

the new chemical program included in an appendix an evaluation of the risks prevented by EPA action (or EPA-induced "voluntary" action by the manufacturer) with respect to nine new chemicals.

> "Our analysis of these nine PMN submissions did not find any case in which EPA action prevented adverse health effect on the order of magnitude similar to those associated with the better-known occupational toxins or environmental pollutants. In the two instances (four chemicals) where quantitative assessments of risk reduction were developed, the estimated number of cancer cases prevented is much less than one."10/

This sample was small, and the results were not intended as a measure of the total benefits of the new chemical program--the RIA points out, for example, that PMNs would never be submitted for very risky chemicals. Nonetheless, it confirms the subjective impression that the risks addressed in PMN reviews are smaller than those that ordinarily would be judged to warrant federal intervention--not simply by an order of magnitude, but by perhaps half-a-dozen orders of magnitude. This raises serious questions about the cost-effectiveness of the program.

In addition, there are cases where EPA has kept off the market chemicals that were safer than the chemicals they would have substituted for, so that aggregate risk may have increased. Such perverse results can arise from applying a much stricter standard of review to new chemicals.

COSTS AND COST-EFFECTIVENESS

The direct costs to manufacturers of filling out the PMN form and waiting the 90+ days for review (estimated to be three to ten thousand dollars per chemical) are only the most visible cost of PMN reviews. The PMN program makes R&D aimed at developing new chemicals a less attractive investment by raising development costs, aggravating the commerical risks, reducing the rate of return, and compromising the confidentiality of research results.

The individual regulatory actions taken with respect to new chemicals are invariably minor in their immediate impact, but the cumulative effect of the program is to create a substantial barrier to innovation. This effect is very difficult to quantify, but if the effect on chemical innovation and productivity growth resembles past experience in drugs and

---

10/ ICF, Inc.; for EPA. Final Regulatory Impact Analysis for New Chemical Reporting Alternatives under Section 5 of TSCA. ("RIA") February 1983; Appendix F, p. 281. "Less than one" here refers to an annual reduction in total population risk of 10^{-2} to 10^{-5} cancer cases in one instance, and 10^{-4} to 10^{-6} cases in the other, using worst-case assumptions about toxicity and exposure.

pesticides, the cost to the economy could be very large, and one of the nation's most successful export industries could begin to lose markets to foreign competition.

In March 1981, the Council of Economic Advisors and the Council on Wage and Price Stability estimated that the PMN program could conceivably reduce productivity growth in the chemical industry by one or more percentage points annually.11/ A loss of one percentage point would produce a future stream of costs of $336 million annually (based on 1977 value-added data). The present value of this cost stream is $3.3 billion for each year in which such a productivity loss occurs. A $3.3 billion annual cost would be far larger than the direct costs of PMN review, but would be relatively invisible. The actual effect of the PMN program on innovation has not, and perhaps cannot be measured, but this huge potential cost is ample reason for concern.

Most of the actions EPA has taken to control risks of new chemicals are Section 5(e) Orders or Consent Orders. These Orders require testing or other information demonstrating that a suspected risk is not real, and "pending development of information" risk control measures are required. Typically, a manufacturer will agree to use safety controls and comply with paperwork costing only thousands of dollars per chemical to avoid testing that might cost hundreds of thousands of dollars and several years of delay. Whether these costs are justified by the associated risk reduction is difficult to determine in the absence of an unbiased estimate of risks.

It appears that the reporting costs associated with the PMN program have so far exceeded the direct costs of any safety controls required. It is possible to perform very rough cost-effectiveness calculations using these reporting costs. The Regulatory Impact Analysis for the PMN program estimates that the reporting costs of a PMN are between $2840 and $9915 per chemical. EPA spends an additional $7730 reviewing the PMN, for a total cost of $10,570 to $17,645. Using the lower figure, and a 10% discount rate, the annualized cost of a PMN filing is about $1000 per year per chemical.

EPA has taken action on 178 out of 3500 chemicals through January 1984, or about 5% of all PMNs. Nine "action" PMNs were analyzed in Appendix F of the RIA, but only four cases had quantitative estimates of risk reduction achieved. In one case the reduction was 10^{-2} to 10^{-5} cancer cases per year; in the other three the total reduction in risk was 10^{-4} to 10^{-6} cancer cases per

---

11/ Council on Wage and Price Stability. Premanufacture Notification under the Toxic Substances Control Act. March 13, 1981, filed in PMN rulemaking docket at EPA; p. 46.

12/ Of the other five chemicals one was thought to be, but turned
(Footnote continued)

year.12/

If one supposes that in 5% of PMNs reviewed EPA is able to take action to achieve a reduction in mortality risk of 10^{-4} on average, one can calculate a cost-effectiveness ratio of \$10,000/(.05 X 10^{-4}) or \$200 million per death avoided.

Obviously, this is not a reliable number. The assumptions underlying EPA's risk estimates are based on worst-case assumptions about risks and exposure; unbiased risk estimates might produce a cost-effectiveness value several orders of magnitude more expensive. Moreover, this estimate includes no costs at all for tests that may be undertaken or for any of the regulatory controls that are used to reduce risks. Neither does it include any costs for the PMN program's effects on innovation and productivity; only the initial PMN reporting and review costs are included.

On the other hand, environmental risks and less serious health risks are not included. Moreover, even one large risk prevented by the PMN program could make it appear much more cost-effective, assuming that this large risk would not have been reduced by private incentives, by the existing chemical program, by OSHA, or by other risk-reduction programs. The RIA suggests that very risky chemicals would not likely be submitted for PMN review in the first place, and attributes unquantified benefits to this "deterrent" effect. (Of course, the deterrent effect only applies to chemicals known in advance to be hazardous, and implicitly supposes that these chemicals would have been marketed in the absence of the PMN program.) There are many other shortcomings in the cost-effectiveness calculation, but it tends to confirm the subjective impression one gets from looking at the PMN review experience to date: it consumes a lot of resources, both private and public, and produces very little identifiable

---

12/ (continued)
out not to be, a skin irritant. Hence there were costs and delays, but no risk reduction. On three others the risks were so speculative as to be unquantifiable, in one other case the risk appeared to be zero. Five more cases were discussed in a slightly different context in Chapter VII of the RIA. In two cases chemicals were kept off the market that would have displaced other chemicals of similar toxicity. In one case it appears EPA action may have increased total risk, in the other case it may have decreased it--the net effect is unknown. Another chemicals could have resulted in 0 to 48 cases of "toxic effects, some of which, perhaps the majority, would be asymptomatic." No fatalities were expected. One other chemical could conceivably produce 10^{-4} cancers per year, with EPA action having negligible effect on this risk. The last chemical could have produced up to 40 cases of skin or eye irritation. These fourteen chemicals are not a random sample of PMNs.

risk reduction.

PMN reporting and review are required by TSCA. Cost-effectiveness comparisons can still be used, however, to make resource allocation decisions, to set regulatory priorities, to fine tune the reporting form, and to develop risk-management guidance. They can also be used to make decisions about whether to extend the PMN program to new areas (such as export chemicals and biotechnology) or whether to provide PMN exemptions for relatively low-risk categories of chemicals.

REAGAN ADMINISTRATION INITIATIVES

Concern for the effect of the PMN program on innovation, productivity, and trade prompted the Presidential Task Force on Regulatory Relief to request a review of the program and to ask EPA to develop categories of chemicals that could be exempted. The Act provides for exemptions from PMN review for categories of chemicals that will not present an unreasonable risk. The initiative was intended to provide exemptions for three major categories of chemicals for which PMN review appeared unnecessary: polymers, low-volume chemicals, and site-limited intermediates. Polymers (plastics, textiles, and related compounds) present little risk because their molecules are too large to be absorbed through biological membranes. Chemicals that are produced in low volumes or that never leave the site where they are created are low in risk because exposure is inherently limited. Together these categories were believed to cover two-thirds of all new chemicals. Exemptions would have allowed EPA to concentrate its resources on the remaining third where significant risks are much more likely to be found (and, of course, on the multitude of existing chemicals). Exempting polymers and low-volume chemicals would, it was believed, have a particularly favorable effect on innovation.

In the draft rules that have been sent to OMB the categories have been narrowed, so that the maximum coverage of the exemptions would be about one-third of new chemicals. A greater drawback, however, is that they do not provide a real exemption from PMN review, and in many cases may be more onerous than a normal PMN review. As a result, it is unlikely they would ever be used at all.

Two related rules are also under review at OMB. EPA has submitted a proposed rule to subject to PMN review chemicals that are manufactured solely for export. Export-only chemicals are specifically excluded from the PMN requirement by the Act, but the agency is proposing to use a separate data collection authority to impose requirements virtually identical to the PMN requirement.

The second rule also relates to an exemption. TSCA generally authorizes EPA to collect data from a manufacturer of any commercial chemical, but provides an exemption to small firms. EPA has developed a rule that would deny this exemption to manufacturers of chemicals introduced since 1979, when the PMN program began. This is the first step in a program to "monitor" all post-1979 chemicals, putting them on a different footing from pre-1979 chemicals and possibly further chilling new chemical innovation.

The Exemption Rule for Polymers

In response to Section 5(h)(4) of the TSCA, petitions by several chemical industry groups, and a request by the Presidential Task Force on Regulatory Relief, EPA has developed a draft rule exempting polymers from some premanufacture notification requirements.

To grant an exemption under Sec. 5(h)(4), EPA must:

- design an appropriate category of chemical substances;
- specify which PMN requirements they will be exempt from; and
- make the statutory determination that the chemicals in the exempt category will not present an unreasonable risk to human health or the environment.

The unreasonable risk determination involves a balancing of any risks likely to be created by the exemption against the benefits of the exemption. It is made for the category as a whole: EPA need not, and indeed probably could not, draw conclusions with respect to each possible future chemical that might be exempt.[13]

The rationale for designating polymers as an exempt category is the size of the molecules. In most cases polymer molecules (such as plastics or textiles) are simply too big to pass through biological membranes, and hence cannot be toxic. There are exceptions to this generalization, such as low molecular weight polymers, polymers that decompose, polymers with highly reactive side groups or metal ions, and water soluble polymers that may be troublesome in the aquatic environment. All of these have been excluded from the category EPA has defined. The remaining members of the category are truly innocuous.

The exemption that EPA has drafted for the polymer category is a very limited one. Indeed, it exempts the chemicals from so little, and adds such conditions to the exemption, that it seems unlikely anyone would ever choose to use the exemption. As a result, the draft rule provides very little public benefit. The table below compares the requirements for a PMN notice, for the polymer exemption EPA has drafted, and for a more complete polymer exemption OMB would propose.

---

[13] "It should be noted that in taking action under any provision of the bill respecting a category of chemical substances, the Administrator will not have to make the requisite finding for such action with respect to every chemical within the category." (Report of the House Committee on Interstate and Foreign Commerce on the Toxic Substances Control Act. p. 61.)

Regular PMN	Draft Exemption	OMB Changes
90-day notice; extendable to 180 days.	21-day notice; extendable to 180 days.	0-day notice; not extendable.
Notice includes identity, use, production volume, byproduct, exposure, and disposal data.	Notice includes identity, use, production volume, byproduct data, plus eligibility demonstration.	Notice includes identity and eligibility demonstration.
During review, Section 5 Orders may be used to restrict chemical.	During review, Setion 5 Orders may be used to restrict chemical.	Section 5 orders may not be used; risks will be controlled by rulemaking, as with any existing chemical.
Chemical added to inventory without restrictions, unless a risk is identified.	Chemical added to inventory with restrictions on exact composition and production methods, even absent any risk.	Chemical added to inventory without restrictions.

Compared to full PMN review, EPA's draft exemption provides a shorter review period. Since it is extendable to the full 180 days, however, it provides little certainty to manufacturers about when manufacture may begin. The amount of data included in the exemption notice is still significant, and EPA resources will be used in reviewing these notices. We believe it would be more productive simply to add polymers to the inventory without review, allowing EPA resources to be directed towards chemical categories that are likely to present more risks. The administrative orders authorized by Section 5 need not be applied to polymers (they never have been, and probably never would be in any case); exempting this category from such orders in advance will provide more certainty for manufacturers that there will be no delays or interruptions in production. Other TSCA authorities will be available in the unlikely event that a member of the exempt category turns out to be risky. Finally, in the absence of any finding of risk, there is no reason to place composition and production restrictions on polymers when they are added to the inventory. Under the EPA draft exemption, minor variations from the original polymer formulation would trigger the PMN requirement anew. As a result, the exemption offers few advantages to a manufacturer, and many drawbacks, compared to full PMN review. Manufacturers would rarely, if ever, opt for the exemption.

Cost-effectiveness calculations could help make the case for exempting polymers. Risks associated with polymers are expected to be smaller and less frequent than risks found among other chemicals. The cost-effectiveness of PMN reporting requirements for polymers might therefore be in the billions or trillions of dollars per statistical mortality, or some other measure of risk. Taking into account the additional effects on innovation, it should not be difficult to determine that a complete exemption from PMN review would not create an unreasonable risk.

Since the category of eligible polymers does not include any chemicals that have been hazardous in the past, and is unlikely to include any in the future, it appears much more desirable to exempt the category from PMN review altogether. Polymers are an active area of innovation, and the benefits of an exemption would undoubtedly be more than sufficient to outweigh any small risks. In the rare cases when an unforseen risk does appear, TSCA gives EPA sufficient authority under other sections of the Act to control it.

EPA should rewrite its polymer exemption rule to provide a more complete exemption from PMN reporting and review requirements.

The Exemption Rule for Low-volume Chemicals and Site-limited Intermediates

Under EPA's draft rule, persons requesting a PMN exemption for site limited or low volume chemicals must notify EPA 21 days before manufacture. To qualify for an exemption, site limited chemicals must pass certain exclusion criteria (i.e. non-carcinogenic, non-teratogenic and not acutely toxic). The applicant must also submit a qualified expert's review which must answer why, based on toxicity and exposure, the chemical poses no unreasonable risk. Manufucture may begin at the end of 21 days if EPA agrees. However the chemical is not placed on the inventory. The applicant is requested to submit a further notice if here there is any change in volume produced.

The low volume exemption is divided into two categrories: less than 1,000 kg and 1,000 to 10,000 kg. The 1,000 to 10,000 kg provision is analagous to the site limited exemption. It contains the same exclusion criteria and requires an expert review. Furthermore, the chemical is not placed on the chemical inventory and the applicant must submit a new notice if site of manufacture or use changes.

The less than 1,000 kg exemption contains no exclusion criteria and does not require an expert review, but the chemical does not reach the inventory and is subject to the same changes in use or site of manufacture requirements as the 1,000 to 10,000 kg substances. Both low volume exemptions are subject to revocation if another person submits a notice for the same chemical. The rationale is that if another person manufacturers the same chemical, the low volume status no longer applies.

Lastly, the rule requires manufacturers of all exempt chemicals (except polymers) to maintain production volume records for five years. Manufacturers must also maintain documentation of information in the exemption notice (i.e. the experts review) and documentation of compliance with the terms of the exemption for five years after commencement of manufacture. Under the normal PMN process, manufacturers are required to maintain production volume and compliance data for only three years after commencement of manufacture.

Under this exemption rule, manufacturers fill out only a limited portion of the PMN form; however, the expert review in effect constitutes completion of the entire form. The expert is not only required to verify compliance with the eligiblity criteria, but also present detailed exposure and toxicity analysis. With the exception of the less than one 1000 kg provision, manufacturers will face the same or greater direct form-filing costs as under the normal PMN.

Because the applicant may begin manufacture at the end of 21 instead of 90 days, delay costs will be reduced, but this benefit may be offset by the fact that manufactures must resubmit a notice if site of manufacture or use changes. Under the normal PMN process, no additional notices are required once a chemical has passed review (unless it is a high risk chemical, which would not be eligible for exemption).

The benefits of an expedited review are further reduced by the imposition of recordkeeping requirements more burdensome than the normal PMN requirements. This additional burden will fall most heavily on small firms (more likely than large firms to be manufacturing low-volume chemicals), and is unwarranted in view of the low risks involved.

The expert review provisions of this rule should be replaced by a simple certification provision, and the reporting and recordkeeping requirements should be reduced to the minimum necessary to assure that the exemption will produce benefits in excess of any risks.

The Extension of PMN Requirements to Export-only Chemicals

Unless they are found to present an unreasonable risk to the United States, chemicals destined solely for export are exempt from all provisions of TSCA except Section 8, which authorizes recordkeeping requirements and collection of certain data. They need not be listed on the inventory of existing chemicals in order to be manufactured, and they do not have to undergo premanufacture review unless, and until, someone proposes to use them domestically.

EPA recently submitted a proposed rule under the authority of Section 8 whose provisions are virtually identical to the premanufacture reporting requirements of Section 5. Under this rule, all existing export-only chemicals would have to submit PMN notices within thirty days of the rule's effective date, and all future export-only chemicals would have to submit PMN notices within thirty days of the decision to export.14/ This notice is in addition to the PMN notice the Act requires prior to any domestic use of a chemical.

The rationale for doing this is unclear. Common sense tells us that exporting a chemical is generally less risky than using it domestically. International convention leaves the responsibility for regulating chemical risks primarily with the importing country. Cognizant of this, Congress exempted export-only chemicals from PMN requirements unless domestic use is contemplated, and clearly intended that they should receicve a lower level of regulatory attention than that accorded to domestic chemicals.

The EPA proposal turns common sense, international convention, and congressional intent upside down. PMN submissions would be required for all export chemicals, whereas it is only required for new domestic chemicals. Rough calculations could be used to demonstrate that PMN reporting for export chemicals is unlikely to be cost-effective.

Extending the PMN program to all export chemicals will put U.S. firms at a disadvantage, particularly for specialty chemical orders. EPA has not provided an adequate rationale for this rule, it should be disapproved under the Paperwork Reduction Act and Executive Order 12291.

14/ Because they do not appear on the inventory, all export-only chemicals are technically "new" chemicals under TSCA, even though they may have been produced for many years. ("New means "not on inventory.")

The Exemption Rule for Reporting from Small Manufacturers

TSCA Section 8(a)(1) authorizes EPA to require manufacturers or processors to submit reports and maintain records "necessary for effective enforcement of the Act." However, it explicitly exempts small manufacturers and processors, as defined by EPA in consultation with the Small Business Administration, from Section 8(a)(1) rules. EPA has submitted to OMB a final rule defining "small manufacturers" (not processors)--seven years after the Act passed. Up until now, the agency has allowed exemptions on a case-by-case basis.

As originally proposed in 1982, the rule would have applied to all manufacturers meeting certain revenue and production volume criteria (30 million dollars and 100,000 lbs./yr.). The final rule applies only to manufacturers of chemicals that were not subject to the Premanufacture Notification process (i.e., pre-1979 chemicals). The rule is the first to draw an explicit legal distinction between pre-1979 and post-1979 chemicals, so it will be viewed as an important precedent. If the industry perceives that post-1979 chemicals will always be subject to closer scrutiny and more burdensome regulation, innovation could decline still further. It is particularly disturbing that the rule under review would focus this effect on the small manufacturers.

In the preamble to the draft rule, EPA asserts the right to modify the definition of "small" for any particular future recordkeeping or reporting requirement if the agency decides that it "needs" the information.15/ The statute, on the other hand, provides a specific set of prerequisites that EPA must meet before overriding the exemption. In the absence of a reliable generic definition small manufacturers can not be sure whether they will be subject to reporting and recordkeeping rules, making it difficult to plan for compliance.

The Congress intended to minimize reporting burdens under TSCA, particularly for small businesses:

> "To the extent feasible, the Administrator shall not require unnecessary or duplicative reporting. The Committee realizes that recordkeeping and reporting may be a time-consuming and resource-consuming undertaking. Under section 3503 of title 44 of the United States Code (the Federal Reports Act), the Office of Management and Budget is required to review the collection of

---

15/ For example, the reporting rule discussed above for export-only chemicals includes an ad hoc definition of small manufacturer that would override the generic definition. Among other things, to be eligible for exemption the manufacturer could not make more than 100 kg/yr--about a cup and a half a day.

> information required by the Environmental Protection Agency to assure that such information is obtained with a minimum of burden on business enterprises and other persons and that unnecessary duplication is avoided. The Committee intends that every effort be made to realize this objective."16/

EPA should develop a generic definition of small manufacturer that covers all chemicals, both old and new, and should make make ad hoc revisions in the definition only for exceptional situations where they may be justified.

16/ Report of the House Committee on Interstate and Foreign Commerce on the Toxic Substances Control Act. p. 42.

The Extension of PMN Requirements to Biotechnology

Biotechnology refers to the emerging industry whose products or production processes include organisms modified by recombinant DNA or other recently developed methods of genetic manipulation. Currently the biotechnology industry is not regulated *per se*, but is subject to the same regulatory controls as other technologies. That is, the Food and Drug Administration must approve new drugs, EPA must approve new pesticides or new chemicals, OSHA may regulate the workplace, and so forth.

In the mid-seventies widespread fears of an ecological disaster or a novel disease gave rise to proposals for regulation of genetic engineering both at the federal and the local levels. No federal legislation ever passed, but the National Institutes of Health set up a Recombinant-DNA Advisory Committee (RAC)17/ and issues guidelines to control federally funded research projects. The more exotic public fears abated as understanding of genetic engineering improved, and the guidelines have several times been relaxed. All research in this area has been conducted under the guidelines, whether or not federal funds were involved, and all biotechnology companies have sought the approval of RAC (not always successfully) before trying anything new.

Biotechnology research is now bearing fruit and companies are beginning to market products (chiefly animal and human drugs, fermentation cultures, and agricultural products). RAC is increasingly asked to review proposals that go beyond laboratory research--including proposals for the deliberate release of genetically modified organisms. Last year, to the surprise of everyone, including RAC, EPA announced that the Toxic Substances Control Act gave the agency general authority to regulate all genetic engineering.

DNA, the agency argues, is a chemical substance, and modified DNA is therefore a "new chemical substance." Hence all products of DNA (or RNA) manipulation would be subject to the PMN requirements of TSCA. It is impossible to evaluate the risk associated with DNA without looking at the whole organism so, by extension, genetically modified organisms would have to be evaluated by EPA prior to commercial use.

There are both legal and scientific problems with this assertion of jurisdiction. EPA acknowledges that the plain meaning of the words "chemical substance" in TSCA does not appear to encompass all living things. It also acknowledges that the legislative history reveals no congressional intent to include living organisms under the Act. Nonetheless, the agency argues that

---

17/ This group includes representatives from affected federal agencies, as well as outside experts.

TSCA was intended to be a "gap-filling" statute. The agency perceives a regulatory gap in biotechnology (since RAC has no formal regulatory authority), and has stepped in to fill it.

The scientific problems with EPA's assertion stem from the fact that genetic material is constantly changing, with or without human intervention. It is therefore impossible to list all "existing" genes and equally impossible to define unambiguously "new" genetic material. Moreover, mankind has deliberately manipulated genotypes for millenia, through selective breeding. Some methods of genetic engineering predate the evolution of sex itself, although they have only been understood more recently. The notion of "deliberate" modification may not be of much use in defining new products, since it is still true that many discoveries in this field are more fortuitous than deliberate. EPA is struggling to develop definitions that allow it to regulate biotechnology without getting in the way of evolution and traditional breeding.

Legal and scientific questions aside, the appropriateness of using TSCA as the basic statute for regulating biotechnology has never been considered either by the Congress or by the Cabinet. EPA does not have the expertise in this area that has been assembled in RAC, and the structure of TSCA may not be the best way to regulate this technology. Innovation, particularly at small firms, is not merely important in this industry--it is the industry. Erecting new regulatory barriers without careful consideration of their effects could jeopardize the progress that the U.S., in particular, is making.

EPA should withdraw its expansive interpretation of "chemical substance," and the administration should seek advice from RAC and/or the National Academy of Sciences as to what regulatory authority, if any, might be needed to suplement existing laws.

Recommendations

1) EPA should revise the exemption rules now at OMB so that they provide true exemptions for those categories of chemicals that do not present unreasonable risk.

2) OMB should reject EPA's proposal for extending the premanufacture notification program to export-only chemicals.

3) A Cabinet Council working group should be created to develop recommendations for regulating biotechnology; EPA's assertion that TSCA covers these products should be withdrawn.

4) In preparation for the FY86 budget, EPA and OMB should jointly prepare a study of the cost-effectiveness of resources devoted to regulating new chemicals and those devoted to regulating old ones.

5) The administrative distinction EPA has proposed between pre-1979 chemicals and post-1979 chemicals should be dropped, and priorities for regulation should be based on relative risk and its remediability, rather than on vintage.

6) EPA should develop risk assessment and risk management guidance for reviewing new chemicals that results in balanced decisions, based on best scientific estimates of risks rather than worst-case assumptions.

7) EPA, OSHA, and OMB should confer on what degree EPA needs to develop occupational standards for chemicals to supplement OSHA's standards.

8) The reporting exemption in TSCA for small manufacturers should be supported by a generic definition of small manufacturer.

Summary of Florio Reauthorization Bill (H.R. 4304): The Toxic Substances Control Act Improvement Amendments of 1983

New Chemical Provisions:

The definition of "chemical substance" would be amended to include "microorganisms and other biological products." The intent is to require all products of biotechnology to undergo PMN review by EPA.

The bill would require EPA to develop a set of mandatory tests (similar to the guidelines the agency issued previously) to be required of all new chemicals.

The provision of TSCA Section 26(c) that prohibits EPA from regulating new chemicals as a class would be deleted.

An "interim list" of chemicals would be created, separate from the inventory of existing chemicals in commerce, to include any chemicals that, because of an exemption or other reason, had not undergone a complete PMN review, including the new testing requirements.

Issuing "Significant new use rules," which can require multiple PMN reviews for a chemical, would be made easier.

The finding that a new chemical "may present an unreasonable risk" would no longer be necessary before imposing testing requirements and interim controls. EPA would need only find that they had "insufficient data" on a chemical.

Other provisions:

EPA would be given authority to enforce voluntary testing agreements, in lieu of test rules.

EPA would be required to undertake a rulemaking to regulate formaldehyde.

The statutory prohibitions on polychlorinated biphenyls (PCBs) would be slightly relaxed.

The requirement that other laws (such as the Clean Air Act or the Occupational Safety and Health Act) be used in preference to TSCA would be deleted.

The confidentiality protections in TSCA would be relaxed.

The enforcement penalties in TSCA would be increased.

For certain testing requirements, deadlines for completing rulemakings would be added to the existing deadlines for initiating rulemakings.

Premanufacture Notification Provision of TSCA

Except as provided in subsection (h) (Exemptions), no person may manufacture a new chemical substance unless such person submits to the Administrator, at least 90 days before such manufacture, a notice of such person's intention to manufacture such substance.

The notice shall include, insofar as known to the person submitting the notice or insofar as reasonably ascertainable:

- The common or trade name, the chemical identity, and the molecular structure of each chemical substance;
- The proposed categories of use of each such substance;
- Reasonable estimates of the total amount to be manufactured, and reasonable estimates of the amount to be manufactured for each of its proposed categories of use;
- A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance;
- Reasonable estimates of the number of individuals who will be exposed to such substance in their places of employment and the duration of such exposure;
- The manner or method of disposal of such substance;
- Any test data in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of any such substance or article containing such substance, or of any combination of such activities, on health or the environment; and
- A description of any other data concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.

Subject to (confidentiality procedures), such notice shall be made available for examination by interested persons.

Exemptions: The Administrator may, upon application and by rule, exempt any manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment.

(from TSCA Sections 5(a), (d), (h), and 8(a)(2))

STATUTORY RISK ASSESSMENT CRITERIA

OFFICE OF GENERAL COUNSEL

JANUARY 1983

This folder comprises a series of papers summarizing risk assessment criteria that appear in statutes administered by EPA. If the criteria have been interpreted by the courts, the leading decisions are briefly summarized.

The Office of General Counsel has not attempted to present a comprehensive or exhaustive discussion of these factors or of the legal and administrative issues which their implementation may present. Instead, this summary listing provides a ready reference and a starting point for discussion.

STATUTORY RISK ASSESSMENT CRITERIA

STATUTORY PROVISION: Clean Water Act, Section 301(g)

RISK ASSESSMENT CRITERIA:

Section 301(g) authorizes the Administrator, with the concurrence of the State, to modify the "best available technology" effluent limitation requirements of subsection 301(b)(2)(A) for non-conventional pollutants (i.e. other than toxic pollutants, conventional pollutants or the thermal component of the discharge) for any point source which can make a specified showing.

One of the elements to be shown is that the modified requirements "will not interfere with the attainment or maintenance of that water quality which shall assure protection of a balanced population of shellfish, fish, and wildlife, and allow recreational activities in and on the water and such modification will not result in the discharge of pollutants in quantities which may reasonably be anticipated to pose an unacceptable risk to human health or the environment because of bioaccumulation, persistence in the environment, acute toxicity, chronic toxicity (including carcinogenicity, mutagenicity or teratogenicity), or synergistic propensities." Section 301(g)(1)(C).

LEADING CASES:

To date there is no case law interpreting the risk assessment criteria of Section 301(g).

STATUTORY PROVISION: CLEAN WATER ACT, §301(h)

Risk Assessment Criteria

Section 301(h) allows the Administrator to modify secondary treatment requirements for publicly owned treatment works discharging into marine waters. To grant a variance, the Administrator must make seven findings, some of which address risk assessment. The most important is the requirement that the discharge not interfere with the attainment or maintenance of that water quality which assures protection of public water supplies and the protection and propagation of a balanced, indigenous population of shellfish, fish, and wildlife, and allows recreational activities, in and on the water. The applicant must also establish a system for monitoring the impact of the discharge on the aquatic biota.

burden on applicant

LEADING CASE:

NRDC v. *EPA*, 656 F.2d 768 (D.C. Cir. 1981)

Does not directly address risk assessment issues.

STATUTORY PROVISION: Clean Water Act, Section 302

RISK ASSESSMENT CRITERIA:

Section 302 authorizes the Administrator to supplement or replace BAT limitations for a point source ~~of~~ or group of point~~s~~ sources by establishing effluent limitations, including alternative effluent control strategies, "which can reasonably be expected to contribute to the attainment or maintenance of" that level of water quality "which shall assure protection of public water supplies agricultural and industrial uses, and the protection and propagation of a balanced population of shellfish, fish and wildlife, and allow recreational activities in and on the water" in a specific portion of the waters of the United States.

Before setting such limitations, the Administrator shall hold a hearing "to determine the relationship of the economic and social costs of achieving any such limitations ..., including any economic or social dislocation in the affected community ..., to the social and economic benefits to be obtained (including the attainment of the objective of this Act) and to determine whether or not such effluent limitations can be implemented with available technology or other alternative control strategies."

LEADING CASES:

None

STATUTORY PROVISION: Clean Water Act, Section 303(c)

RISK ASSESSMENT CRITERIA:

Under section 303(c), water quality standards consist of the designated uses of the waters involved and water quality criteria for such waters based on such uses. Section 303(c) requires the periodic review and, as appropriate, revision of water quality standards to ensure that such standards are "such as to protect the public health or welfare, enhance the quality of water and serve the purposes of this Act. Such standards shall be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and also taking into consideration their use and value for navigation."

LEADING CASES:

None relating to the risk assessment aspects of section 303(c).

STATUTORY PROVISION: Clean Water Act, Section 303(d)

RISK ASSESSMENT CRITERIA:

Section 303(d) requires each State to identify waters where technology-based effluent limitations are not stringent enough to implement applicable water quality standards. The State is to establish for such waters the total maximum daily load of certain pollutants "at a level necessary to implement the applicable water quality standards with seasonal variations and a margin of safety which takes into account any lack of knowledge concerning the relationship between effluent limitations and water quality."

Each State is also to identify those waters where thermal limitations are not stringent enough to assure protection and propagation of a balanced indigenous population of shellfish, fish, and wildlife. The State is to estimate for such waters the total maximum daily thermal load to provide such assurance, "tak[ing] into account the normal water temperatures, flow rates, seasonal variations, existing sources of heat input, and the dissipative capacity of the identified waters or parts thereof. Such estimates shall include a calculation of the maximum heat input that can be made into each such part and shall include a margin of safety which takes into account any lack of knowledge concerning the development of thermal water quality criteria for such protection and progagation in the identified waters or parts thereof."

LEADING CASES:

None

STATUTORY RISK ASSESSMENT CRITERIA

STATUTORY PROVISION: Clean Water Act, Section 307(a)(1)

RISK ASSESSMENT CRITERIA:

Section 307(a)(1) requires the Administrator to publish a list of toxic pollutants and to add or remove pollutants from this list. Toxic pollutants are subject to effluent limitations representing Best Available Technology Economically Achievable (BAT) and are ineligible for waivers from these limitations on water quality or economic grounds. The initial list specified in the Clean Water Act consisted of 65 pollutants and pollutant families.

Pollutants can be added to or removed from the list after the Administrator "take(s) into account" the

> toxicity of the pollutant, its persistence, degradability, the usual or potential presence of the affected organisms in any waters, and the nature and extent of the effect of the toxic pollutant on such organisms.

In addition, the legislative history indicates that pollutants are not to be removed from the toxic pollutant list "without a clear finding that delisting will not compromise adequate control over the discharge of toxic pollutants." (Cong. Rec. Daily ed. S. 19649).

LEADING CASES:

There have been no court cases construing this provision. Since promulgation of the Act, EPA has deleted three pollutants from the list.

STATUTORY RISK ASSESSMENT CRITERIA

STATUTORY PROVISION: Clean Water Act, Section 307(a)(2)

RISK ASSESSMENT CRITERIA:

Section 307(a)(2) requires the Administrator to issue effluent limitations based on the best available technology economically achievable for all toxic pollutants, and authorizes the Administrator, in his discretion, to issue effluent standards for toxic water pollutants.

Effluent standards for toxic pollutants must "take into account the toxicity of the pollutant, its persistence, degradability, the usual or potential presence of the affected organisms in any waters, the importance of the affected organisms and the nature and extent of the effect of the toxic pollutant on such organisms, and the extent to which effective control is being or may be achieved under other regulatory authority." Section 307(a)(2). In addition, any effluent standard "shall be at that level which the Administrator determines provides an ample margin of safety." Section 307(a)(4).

LEADING CASES:

EDF v. EPA, 598 F.2d 62 (D.C. Cir. 1978). Principal holdings respecting risk assessment:

1. In setting a standard for a chemical for which risks are not well understood, the "ample margin of safety" standard allows EPA to extrapolate from health data regarding other similar chemicals. 598 F.2d at 80-81.

2. EPA may rely on animal studies and evidence on occupational diseases to establish risk to man. 598 F.2d at 86-87.

3. The Administrator "has a 'heavy burden' to explain the basis for his decision to permit the continued use of a chemical known to produce cancer in experimental animals." However, if the evidence is merely suggestive of carcinogencity, the decision to act "has been held to fall within the discretion of the Administrator." 598 F.2d at 88.

Hercules, Inc. v. EPA, 598 F.2d 91 (D.C. Cir. 1978). Principal holdings regarding risk assessment:

1. Effluent standard may be based on generic analysis of sensitive species as representative of those that may be present in any waters, and is not required to tailor a standard to local receiving waters. 598 F.2d at 104-106.

2. It was within EPA's discretion to base effluent standard on laboratory studies and to give less weight to field studies adduced by industry at hearing. 598 F.2d at 107-109.

3. Even if EPA is unable to make an affirmative finding of carcinogenicity, it may rely on concerns about possible carcinogenicity in setting an "ample margin of safety." 598 F.2d at 110.

4. EPA may not base effluent standards on considerations of feasibility. 598 F.2d at 110-114.

STATUTORY PROVISION: CLEAN WATER ACT
SECTION 312 (MARINE SANITATION DEVICES)

Risk Assessment Criteria

Section 312(b)(1) requires the Administrator to promulgate Federal standards of performance ("standards") for marine sanitation devices ("MSD's") designed to prevent the discharge of untreated or inadequately treated sewage into or upon the navigable waters from vessels which are equipped with installed toilet facilities. There is no statutory criteria by which the terms "untreated or inadequately treated" are to be measured.

Section 312(f)(3) provides a mechanism whereby, upon application from a state, the Administrator can totally prohibit the discharge of vessel sewage into certain specified waters within the state if she determines that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for such waters to which such prohibition would apply. There is no statutory criteria by which the terms "safe and sanitary removal and treatment" are to be measured.

LEADING CASES:

None.

STATUTORY PROVISION: CLEAN WATER ACT, SECTION 316(a)

Risk Assessment Criteria

If a permittee can demonstrate that an applicable effluent limitation for a thermal discharge is more stringent than necessary to assure the protection and propagation of a balanced indigenous population of fish, shellfish, and wildlife, the Administrator or State may impose a thermal effluent limitation that will assure ... a balanced, indigenous population ..., taking into account the interaction of the thermal component with other pollutants.

LEADING CASE:

Appalachian Power V. Train, 545 F.2d 1351 (4th Cir. 1976).

Principal holding regarding risk assessment:

> Court rejected the utility industry's contention that compliance with existing State water quality standards constitutes prima facie compliance with §316(a) "balanced, indigenous population" finding.

Statutory Risk Assessment Criteria

STATUTORY PROVISION: Clean Water Act, Section 404(b)

RISK ASSESSMENT CRITERIA:

Section 404(b)(1) requires the Administrator to develop "guidelines" for the specification of disposal sites for the discharge of dredged and fill material in the waters of the United States. These guidelines are to be based upon "criteria comparable to the criteria applicable to the territorial seas, the contiguous zone, and the ocean under section 403(c)."

Section 403(c) in turn requires the development of "guidelines for determining the degradation of the waters" including a number of possible effects of the disposal of pollutants on the environment. If insufficient information exists on any proposed discharge to make a "reasonable judgment" under the guidelines, the discharge shall not be permitted.

LEADING CASES:

None directly.

STATUTORY PROVISION: Clean Water Act, Section 405(d)

RISK ASSESSMENT CRITERIA:

Section 405(d) requires the Administrator to issue regulations establishing guidelines on the disposal and use of sewage sludge. Those guidelines must identify uses of sludge (including disposal) and "identify concentrations of pollutants which *interfere with* each such use or disposal." (emphasis added) The statute does not specifically indicate whether this "interference" test contemplates an assessment of health or environmental risk.

In issuing regulations under Section 405 (*i.e.*, 40 CFR Part 257), EPA has asserted that guidelines "designed to avoid a reasonable probability of adverse effects on health or the environment" are within the scope of EPA's authority under Section 405. See 44 Fed. Reg. 53439.

LEADING CASES:

No cases have considered EPA's authority under Section 405(d) to establish standards based on health or environmental criteria.

could not be ocean-dumped after December 31, 1981. 543 F. Supp. at 1103.

3. EPA must consider the environmental impacts of land-based alternatives in evaluating an ocean-dumping application. 543 F. Supp. at 1105-08.

National Wildlife Federation v. Costle, 629 F. 2d 118 (D.C. Cir. 1980)

Principal holdings respecting risk assessment:

1. The Administrator is not required in enacting ocean-dumping criteria to include all the evaluation factors listed in Section 102(a) of the MPRSA. Rather, he must take them into account in establishing such criteria. 629 F.2d at 135.

2. The Administrator may establish different criteria for dredged and non-dredged materials, but an adequate explanation must be provided for such a difference in treatment. To the extent that they treated dredged and non-dredged material differently, EPA's regulations were vacated for lack of an adequate explanation. 629 F.2d at 135.

STATUTORY RISK ASSESSMENT CRITERIA

STATUTORY PROVISION: Safe Drinking Water Act, Section 1421(b)(1)

RISK ASSESSMENT CRITERIA:

Section 1421 requires the Administrator to promulgate regulations to serve as minimum requirements for state underground injection control (UIC) programs. Subsection (b)(1) specifies that these regulations must ensure that state programs will "prevent underground injection which endangers drinking water sources." There are two criteria for determining whether injection "endangers": whether contamination resulting from injection may cause a violation of primary drinking water regulations, and whether it "may otherwise adversely affect the health of persons." When EPA considers whether the objective standards set forth in the primary drinking water regulations may be violated, no risk assessment is involved. When EPA considers adverse effects to health, some risk assessment is implied.

The UIC regulations have been promulgated pursuant to this authority, and are set forth in 40 C.F.R. Parts 122, 123, 124, and 146. The regulations implement the statutory provisions by technical standards designed to prevent the movement of fluids into underground sources of drinking water, rather than by attempting to create a regulatory risk assessment mechanism. The UIC regulations do not, therefore, require any risk assessment in their implementation. There are no court decisions related to any risk assessment under this statutory provision.

The court also held that the Administrator was not limited to protecting against effects which are known to be clearly harmful to health, but could regulate based on preventive or precautionary considerations. Similarly, the court held that EPA was not obliged to wait for unambiguous evidence of the existence of a harmful effect before making the possibility of that effect the basis of regulation. Against this background the court held that the Administrator had broad discretion to choose the particular effects on which he would base the standards and the weight of evidence he would require that these effects existed and were serious enough to be considered adverse impacts on health.

STATUTORY RISK ASSESSMENT CRITERIA

STATUTORY PROVISION: Clean Air Act, Section 112

RISK ASSESSMENT CRITERIA:

Section 112 of the Clean Air Act requires the Administrator to list each air pollutant

> to which no ambient air quality standard is applicable and which, in the judgment of the Administrator, causes or contributes to air pollution which may reasonably be or anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness.

Within 180 days after listing EPA must propose, and within 180 days after proposing must promulgate, standards that protect the public health against this pollutant with an "ample margin of safety" unless he finds on the basis of evidence submitted during the rulemaking that the pollutant in question "clearly is not a hazardous air pollutant."

These provisions have never been judicially interpreted. However, they have been the subject of extensive administrative consideration revolving around one central issue. If a pollutant is a carcinogen, as most candidates for listing under section 112 are, it is assumed to lack an effects threshold and the argument can then be made that only a standard that forbids emissions altogether can truly protect the public health. Over the years EPA has attempted to fashion a standard for regulation that avoids this position.

In practice, section 112 standards for carcinogens have reflected "best technology", but the Agency has not formally adopted a generic "best technology" approach.

STATUTORY RISK ASSESSMENT CRITERIA

STATUTORY PROVISION: Clean Air Act, Section 211

RISK ASSESSMENT CRITERIA:

Section 211 of the Clean Air Act authorizes the Administrator to regulate or prohibit any motor vehicle fuel or fuel additive which in his judgment "causes or contributes to air pollution which may reasonably be anticipated to endanger the public health or welfare". Before regulating, the Administrator must consider available "medical and scientific" data, including alternative ways of achieving emission reductions, Sec. 211(c)(2)(A). Before prohibiting an additive entirely, he must find that this will not lead to use of other fuels or additives that will have equal or greater effects on health or welfare, Sec. 211(c)(2)(C).

Comp
EPA

LEADING CASES:

The only case to interpret these provisions is Ethyl Corp v. EPA, 541 F.2d. 1 (D.C. Cir. 1976)(en banc). That case involved EPA regulations to regulate lead in gasoline under a prior version of the statute that required EPA to find that emissions of an additive being regulated "will endanger" public health or welfare.

The court rejected the argument that this language requires proof that the additive is causing the harm for which it is being regulated. Focussing on the word "endanger", it reasoned that "danger" can exist where there is a risk of harm as well as where there is the certainty of harm. EPA could therefore regulate based on less than definitive evidence if the danger whose existence the available evidence suggested was great enough. It said these regulations would have to be based on "reasonable medical concerns", and found that the evidence relied on by EPA met this test. Finally, the court held that EPA was not restricted to considering the health impact of lead from leaded gasoline in isolation, but could view it in the context of human exposure to lead from other sources.

In 1977, Congress amended the Clean Air Act to make clear that it agreed with the court's interpretation and to reaffirm the precautionary purposes of section 112.

STATUTORY RISK ASSESSMENT CRITERIA

STATUTORY PROVISION: Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

RISK ASSESSMENT CRITERIA:

The statutory standard for registration of a pesticide under FIFRA requires that the pesticide perform its intended function without causing "unreasonable adverse effects on the environment". § 3(c)(5). The term "unreasonable adverse effects on the environment" is defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide". § 2(bb). In effect, this standard requires a finding that the benefits of each use of the pesticide exceed the risks of use, when the pesticide is used in accordance with commonly recognized practices.

The burden of proving that a pesticide satisfies the standard for registration is on the proponents of registration and continues as long as the registration remains in effect. Under § 6, the Administrator is required to deny or cancel the registration of a pesticide (or suspend the registration under appropriate circumstances) if he determines that the pesticide does not satisfy the statutory standard for registration.

LEADING CASES:

EDF v. EPA, 548 F. 2d, 998 (D.C. Cir. 1976)

1. The applicant/registrant has the burden of proof for establishing the safety of a product. 548 F. 2d at 1004.

2. The type of risk information which has been held a sufficient basis for cancelling or suspending the registration of a pesticide includes "reliance on general data, consideration of laboratory experiments on animals, etc.". 548 F. 2d at 1005.

3. Animal test data is acceptable to evaluate human cancer risks. A positive oncogenic effect in test animals is sufficient to characterize a pesticide as a potential human oncogen. 548 F. 2d at 1006.

4. In order to conclude that a pesticide which is oncogenic in test animals poses an oncogenic risk to humans, the Agency must show that humans will be exposed as a result of the use of the pesticide. 548 F. 2d at 1008.

EDF v. EPA, 510 F. 2d 1292 (D.C. Cir. 1975)

1. "'FIFRA confers broad discretion' on the Administrator to find facts and 'to set policy in the public interest.'" 510 F. 2d at 1297.

2. The Court of Appeals upheld the Agency's determination that the "concept of a threshold exposure level has no practical significance where carcinogens are concerned...due in part to the irreversibility and long latency period of carcinogens." 510 F. 2d at 1298.

3. Animal test data may be validly extrapolated to humans. Even though the "extrapolation of data from mice to men may be quantitatively imprecise, it is sufficient to establish a 'substantial likelihood' that harm will result." 510 F. 2d at 1299.

4. Use of animal data is particularly appropriate where accurate or timely epidemiology studies cannot be conducted. 510 F. 2d at 1299.

5. The court upheld the Agency's finding that "rodents are particularly useful experimental animals, in part because of the similarity of their response to carcinogens to the response of man, their short lifespan, and our relatively well-developed understanding of the pathological development of tumors in mice and rats." 510 F. 2d at 1299.

STATUTORY RISK ASSESSMENT CRITERIA

STATUTORY PROVISION: The Federal Food, Drug, and Cosmetic Act (FFDCA) RISK ASSESSMENT CRITERIA:

Under the Reorganization Plan which established EPA, EPA has the authority to set tolerances (maximum allowable limits of pesticide residue) for pesticide chemicals in raw agricultural commodities and processed food and feed under §§ 408 and 409, respectively, of the Federal Food, Drug, and Cosmetic Act (FFDCA). Without such tolerances, a food is "adulterated" under § 402 of the FFDCA and hence may not legally move in interstate commerce.

The standard for a tolerance or exemption from the requirement of a tolerance for a raw agricultural commodity under § 408 entails a finding that the establishment of the tolerance or exemption would "protect the public health". § 408(b) and (c). In establishing a tolerance regulation, EPA must also make a determination that the pesticide is useful for the purpose for which the tolerance is sought, and must consider, among other relevant factors, the necessity for the production of an adequate, wholesome, and economical food supply, and the other ways in which the consumer may be affected by the pesticide. § 408(b).

In order to establish a food additive regulation for a processed food or feed under § 409, the Agency must make a finding that the pesticide "may be safely used" (§ 409(a)). */

---

*/ A food additive regulation setting a tolerance level must be established for a processed food or feed if the pesticide residue in the processed food or feed is greater than the tolerance established for the raw agricultural commodity. See U.S. v. Ewig Bros., Inc., 502 F.2d 715, 722-723 (7th Cir. 1974)

To determine whether a pesticide use is "safe" under § 409, EPA must consider, among other relevant factors: 1) the probable consumption of the pesticide or metabolites; 2) the cumulative effect of the pesticide in the diet of man or animals, taking into account any related substances in the diet; and 3) appropriate safety factors to relate the animal data to the human risk evaluation. A food additive regulation under § 409 may not be established for a carcinogenic substance because of the "Delaney Clause" (§ 409(c)(3)(A)), which provides that no additive is deemed safe if it induces cancer when ingested by man or animal (or so determined by appropriate tests).

In general, the determination of appropriate tolerance levels entails a consideration of the same data base as that necessary to support the registration of a pesticide product used on food. Under the FFDCA, the individual or entity seeking the tolerance bears the burden of establishing the safety of food bearing pesticide residues at tolerance levels for human consumption.

LEADING CASES:

Continental Chemiste Corp. v. Ruckelshaus, 461 F. 2d 331 (7th Cir. 1972)

(1) The burden of establishing safety for a tolerance rests on the petitioner. 461 F. 2d at 341.

(2) In determining the safety of a food additive, the benefits of the additive must be evaluated as well as the potential for harm (except for oncogenic substances). 461 F.2d at 340.

Bell v. Goddard, 366 F. 2d 177 (11th Cir. 1966)

"The Delaney clause is generally intended to prohibit the use of any additive which under any conditions induce cancer in any strain of test animals." 366 F. 2d at 181.

Environmental Defense Fund v. U.S. Dept. of HEW, 428 F. 2d 1083 (D.C. Cir. 1970)

The Delaney clause does not apply to § 408. Thus, a tolerance for an oncogenic pesticide may be established on a raw agricultural commodity if scientific data demonstrates that the residues are safe for human consumption. 428 F. 2d at 1091-1092.

U.S. v. Bodine Produce Co., 206 F. Supp. 201 (D. Ariz. 1962)

The determination of an adequate margin of safety for use in establishing safe tolerance limits entails a consideration of the practical effect of the daily consumption of food containing pesticide residues.

U.S. v. Goodman, 486 F. 2d 847 (7th Cir. 1973)

The FDA has the discretionary authority to set action levels - the level at which enforcement action will be taken - in the absence of tolerance levels.

STATUTORY RISK ASSESSMENT CRITERIA

STATUTORY PROVISION: Toxic Substances Control Act (TSCA)

RISK ASSESSMENT CRITERIA:

Throughout TSCA, the key regulatory concept is "unreasonable risk." This item is not defined in the statute, although there is something like a definition in Section 6(c)(1), which requires the Administrator in promulgating rules pursuant to Section 6(a) to consider four factors, the first two of which concern risk. These are: the effects of the substance on health and the magnitude of the exposure of human beings, and the effects of the substance on the environment and the magnitude of the exposure of the environment to the substance.*/ In addition, Section 4 of TSCA, which allows the agency to require testing of chemicals, sets out the effects and characteristics for which standards for the development of test data may be prescribed. These could be considered a rough catalogue of some of the elements of risk. The effects include "carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects and any other effect which may present an unreasonable risk of injury to health or the environment." The "characteristics" include "persistence, acute toxicity, subacute toxicity, chronic toxicity, and any other characteristic which may present such a risk." Section 4(b)(2).

---

*/ The other two factors involve consideration of benefits and the economic consequences of regulating.

LEGISLATIVE HISTORY:

Although the statute does not directly provide criteria for risk or for unreasonable risk, the legislative history has some useful discussion of the latter concept. The House report on the bill declined to define "unreasonable risk"

> because the determination of unreasonable risk involves a consideration of probability, severity, and similar factors which cannot be defined in precise terms and is not a factual determination but rather requires the exercise of judgment on the part of the person making it . . .

But the Report went on to say,

> In general, a determination that a risk associated with a chemical substance or mixture is unreasonable involves balancing the probability that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture taking into account the availability of substitutes for the substance or mixture which do not require regulation, and other adverse effects which such proposed action may have on society.

TSCA Legislative History at p. 421-22.

There is also legislative history which indicates that in its examination of risk, the agency - in order to guard against effects which may not be "presently visible" - is to act

> not only [on] consideration of facts but also on consideration of scientific theories, projections of trends from currently available data, modeling using reasonable assumptions, and extrapolations from limited data. Furthermore, regulatory action may be taken even though there are uncertainties as to the threshold levels of causation.

TSCA Legislative History at 439.

Finally, there is legislative history endorsing the use of animal studies as a basis for regulation.

> The validity of applying animal test results to man is now firmly based upon empirical evidence and thus such results provide an invaluable tool for predicting human health effects . . . . Although testing and monitoring may not be able to provide certainty as to the long-term consequences resulting from exposure to a chemical, the predictions from such testing and monitoring can provides a reasonable basis for regulatory action to protect against long-term adverse effects. TSCA Legislative History at 413-14.

CASES:

There are no cases directly construing the TSCA unreasonable risk criteria. However, in EDF v. EPA, 636 F.2d 1267 (D.C. Cir. 1980), the Court found that it was appropriate for EPA to consider the criteria set out in Section 6(c)(1) of TSCA. What was at dispute here, however, was not consideration of risk, but consideration of the costs of regulation.

RESOURCE CONSERVATION AND RECOVERY ACT (RCRA)

1. STATUTORY PROVISION: RCRA, Section 1004(5)

RISK ASSESSMENT CRITERIA: RCRA defines the term "hazardous waste" as:

> a solid waste, or combination of solid wastes, which, because of its quantity, concentration, or physical, chemical or infectious characteristics may--
>
> (A) cause or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or
>
> (B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed (Section 1004(5)).

We use this definition in listing hazardous wastes and developing hazardous waste characteristics under Section 3001, conducting inspections and gathering information under Section 3007, and in issuing orders under Section 3013. States must use this definition in developing a hazardous waste site inventory under Section 3012.

LEADING CASES: None.

2. STATUTORY PROVISION: RCRA, Sections 3002, 3003, and 3004.

RISK ASSESSMENT CRITERIA: Sections 3002, 3003 and 3004 require EPA to establish standards for hazardous waste generators, transporters and treatment, storage and disposal facilities "as may be necessary to protect human health and the environment."

LEADING CASES: None

3. STATUTORY PROVISION: RCRA, Section 4004.

RISK ASSESSMENT CRITERIA: Section 4004 of RCRA requires EPA to promulgate criteria for determining which facilities handling non-hazardous solid waste shall be classified as "sanitary landfills" and which shall be classified as "open dumps." A facility may be classified as a "sanitary landfill" only if "there is no reasonable probability of adverse effects on health or the environment from disposal of solid waste at such facility" (Section 4004(a)).

LEADING CASES: None.

STATUTORY RISK ASSESSMENT CRITERIA

STATUTORY PROVISION: CERCLA, Section 102(a)

RISK ASSESSMENT CRITERIA:

Section 102(a) requires the Administrator to promulgate regulations designating as hazardous substances, such elements, compounds, mixtures, solutions and substances which, when released into the environment "may present substantial danger to the public health or welfare." In addition, this section requires the Administrator to promulgate regulations establishing "that quantity of any substance the release of which shall be reported pursuant to section 103."

The legislative history emphasizes that, unlike Section 311 of the Clean Water Act, hazard and harm need not be considered in establishing "reportable quantities." There is no case law addressing these provisions.

STATUTORY PROVISION: Comprehensive Environmental Response, Compensation, and Liability Act, Section 105(8)(A)

RISK ASSESSMENT CRITERIA:

Section 105 requires the President (authority delegated to the Administrator) to revise the National Contingency Plan. The revised Plan is to include criteria for determining priorities among releases for the purpose of taking remedial action. These criteria and priorities are to be used in developing a national priority list which the Agency proposed on December 30, 1982.

Section 105(8)(A) provides that the criteria and priorities are to be based upon "relative risk or danger to public health or welfare or the environment." In making this determination, the Administrator is to take into account (1) the population at risk, (2) the hazard potential of the hazardous substances being released, (3) the potential for contamination of drinking water supplies, (4) the potential for direct human contact, (5) the potential for destruction of sensitive ecosystems, (6) State preparedness to assume costs and responsibilities, and (7) other appropriate factors.

LEADING CASES:

No cases addressing this issue.

U.S. DEPARTMENT OF LABOR
SECRETARY OF LABOR
WASHINGTON, D.C.

JUL 17 1984

Honorable James H. Scheuer
Chairman, Subcommittee on Natural Resources,
Agricultural Research and the Environment
Committee on Science and Technology
Suite 2321 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letter of April 23, requesting the assistance of the Department of Labor in the Subcommittee's consideration of H.R. 4192. Enclosed are the responses of the Occupational Safety and Health Administration (OSHA) to each of the questions posed in your letter. Risk assessment is an important component of the standards established by the Occupational Safety and Health Administration. We are very pleased to assist you in examining this important issue.

If we can be of any further assistance in this matter, please contact Becky L. Rose, Special Assistant for Congressional Relations, Occupational Safety and Health Administration, at 523-6027.

The Office of Management and Budget advises that there is no objection to the submission of this report from the standpoint of the Administration's program.

Sincerely,

Raymond J. Donovan
Raymond J. Donovan

Enclosures

Responses to Questions on Risk Assessment:

1. List, and briefly describe, all uses of risk assessment within the agency.

   Response: Risk assessment is an integral part of OSHA's standards-setting process. OSHA's analytic approach for setting health and safety standards is a four-step process consistent with provisions of the Occupational Safety and Health Act of 1970 and with recent Federal court interpretations of that statute. During the first step, risk assessments are performed in determining whether the hazard to be regulated poses a significant risk to workers. Next, OSHA considers which, if any, of the possible approaches to regulating the hazard will substantially reduce its risk to employees. In the third step, OSHA considers the best available data to establish the most protective exposure limit that is both technologically and economically feasible. As the final step, OSHA considers the most cost-effective way to achieve the regulatory objective.

2. Indicate the total number of "risk assessments" completed and in progress during the last twelve months. For such "risk assessments," indicate the total cost to the agency, including separate figures for staff resources and consultant or contractual expenses incurred.

   Response: During the past twelve months, OSHA initiated and completed risk assessments for workplace exposure to asbestos, benzene, ethylene dibromide (EDB) and ethylene oxide (EtO). Because risk assessment is an integral part of the standards-setting process, OSHA has not developed separate risk assessment documents for other comprehensive health standards or safety standards, but has, instead, incorporated an assessment of the risks involved in the preamble to the rule or proposal. Examples of this treatment of risk assessment are found in OSHA proposals for grainhandling facilities, field sanitation, and oil and gas well drilling and servicing.

   Since information on risk generally emerges as part of the standards-development process along with various other kinds of data, it is not possible to state with accuracy the total cost of risk assessments per se.

In working on a standard, OSHA staff may not devote attention solely to risk assessment, but are likely to address the question of risk along with a variety of other issues. Because of constraints on staff resources, OSHA has at times contracted with private sector firms or individuals for risk assessment studies. The costs of those "outside" studies are of course available. To those costs we have added estimates of the cost of staff time expended on inhouse risk assessment activity and have developed the following rough estimates:

Risk assessment for EDB .... including OSHA staff costs of $ 7,500.	$17,500
Risk assessment for EtO .... including OSHA staff costs of $11,800.	$21,800
Risk assessment for Formaldehyde .... (in 1982)	$53,250
Risk assessment for Asbestos .... including OSHA staff costs of $27,000.	$48,000
Risk assessment for Benzene .... including OSHA staff costs of $19,500	$29,500

3. Indicate the extent to which risk assessments conducted by the agency include the elements set out in section 107(a) of Title I of H.R. 4192.

Response: Element 1 of section 107(a) is the "comparison of risk or alternative courses of action." All OSHA risk assessments consider comparisons of risk and alternative courses of action such as the risk of regulating versus the decision not to regulate. The Agency also studies the risks associated with altenative permissible exposure limits for toxic substances.

Element 2 is the "delineation between scientific and policy judgments." In its risk assessments, OSHA states the assumptions behind its assessment of risk and explains whether those assumptions are based upon scientific criteria or on policy judgments.

Element 3 is the "description of the present roles, if any, of technical or scientific advisory boards with respect to risk assessment." OSHA does not usually employ technical or scientific advisory boards in developing risk assessments. In preparing its proposed standard for grain handling facilities, however, the Agency relied largely on information on risk provided by the National Materials Advisory Board of the National Academy of

Sciences. OSHA generally seeks comments on the validity of risk assessments through contracts with experts in the particular subject being considered for regulation. In addition, scientific and technical comment may be received when Agency risk assessments are placed in the public record with opportunity for public comment.

Element 4 is the "identification of specific assumptions, guidelines, models, and uncertainties." OSHA's risk assessments identify specific assumptions, guidelines, models, and any uncertainties that surround the data on risk. For example, the Agency's ethylene oxide proposal contained the following subheadings in its risk assessment sections:

(a) Data Base for Quantitative Risk Assessment
(b) General Assumptions
(c) Statistical Methods and Predictions
(d) Other Models
(e) Other Risk Assessments
(f) Dose-Response Analysis
(g) Significance of Risk

OSHA also cites confidence limits for risk estimates and discusses any uncertainties of such estimates, such as the incorporation of exposure data in the asbestos proposal.

Element 5 is the "identification of limitations placed on the assessment due to relevant scientific, organizational, and statutory constraints." Each of these factors is addressed in the preliminary risk assessment which is part of every proposed OSHA standard.

Element 6 is the "identification of specific trade-offs posed in the particular risk assessment." OSHA includes this element in the preliminary risk assessment which is part of every standard proposed by the Agency.

Element 7 is "suggestions of how additional information, or changes in statutory language and organizational structure, could change the strategies chosen in risk asssment." Where appropriate, these issues are discussed in the preliminay risk assessment contained in OSHA's proposed standards.

Element 8 is the "discussion of how comparative risk assessment could be utilized to make the public aware of the relevance of the decisions, including a consideration of similar risks, man-made versus natural risk, and necessary versus unnecessary risk." OSHA addresses the issue of comparative risk only with respect to workplace risks. These comparisons are found in the sections of its risk assessments dealing with the significance of the risk.

Element 9 is the "delineation of information concerning the different levels of risk to health and welfare among different groups within the population, including consideration of socioeconomic, geographic, and other pertinent factors, to assist in the equitable sharing of the risks and benefits (including those that can and cannot be quantified in monetary terms) to be realized from the regulatory process and the implementation of public policy." OSHA's regulatory impact analyses, which are developed for all proposed and final standards, address the question of distribution of risks and benefits of regulation among different populations and industries. These issues consequently are therefore not addressed specifically in the risk assessments for proposed or final standards.

4. Indicate the extent to which the Agency makes its risk assessments, and any guidelines under which risk assessments are prepared, available to the public or to the scientific community.

Response: Risk assessment information developed by OSHA and the methodology used in risk assessment are included in OSHA's proposed and final standards as published in the Federal Register. Often, private periodicals, such as the Occupational Safety and Health Reporter, publishd by the Bureau of National Affairs, also print the entire proposal or final rule. Risk assessments prepared for OSHA by private sector sources sometimes appear in scientific or technical journals. For example, a risk assessment prepared for OSHA on formaldehyde, entitled "Formaldehyde Risk Assessment for Occupationally Exposed Workers," was published in Regulatory Toxicity and Pharmacology, 3:355-371, 1983. All risk assessments used in OSHA rulemaking become part of the public record and are available at the Agency's Docket Office in Washington, D.C. Another vehicle for disseminating risk analysis information is the OSHA-ANSI Coordinating Committee. This is a joint effort of OSHA and the American National Standards Institute, an organization comprised of member associations that develop voluntary, consensus safety standards. OSHA shares information with ANSI on assessment of risks related to safety hazards, and ANSI in turn makes these data available to its member associations and firms.

5. Describe any efforts the agency has made within the last two years to improve or expand the use of risk assessment within the agency, including any efforts to improve intra-agency coordination of risk assessments or the developments of any guidelines or protocols for risk assessments.

Response: OSHA has taken steps to improve its capability to conduct risk assessments. An Office of Risk Assessment has been established in OSHA's Directorate of Health Standards Programs to ensure that risk documents are prepared in a thorough and timely manner. This is the first time OSHA has devoted an office solely to preparation of risk assessments. The Agency expects to add additional health scientists and statisticians to the existing office staff. The Office of Risk Assessments is also responsible for interagency coordination. The Director of the Office recently spent four months working at the headquarters of the Environmental Protection Agency (EPA) in order to understand EPA's risk assessment procedures. In the area of occupational safety, OSHA is improving its risk assessment capability by improving its use of Agency Fatality/Catastrophe reports. These reports, which employers are required to submit to OSHA when workplace fatalities or multiple serious injuries occur, are now being computerized, catalogued, and placed on microfiche so that accident data may be quickly retrieved for use in standards development. These data help OSHA estimate the risk of various safety hazards.

6. Describe any efforts the agency makes to coordinate its risk assessments or its risk assessment procedures with other Federal agencies.

Response: OSHA provides drafts of its risk assessment documents to other Federal agencies such as EPA and NIOSH (the National Institute for Occupational Safety and Health) for review and comment, and in turn reviews drafts of risk assessment documents prepared by other regulatory agencies. Thus, valuable comments are exchanged. OSHA has also used data on grain elevator explosions prepared by the Federal Grain Inspection Service and data on wheel rim explosions developed by the National Highway Traffic Safety Administration to assist the Agency in writing standards for grain elevators and wheel rims, respectively. OSHA also participates in the Interagency Risk Management Council. This council includes the Environmental Protection Agency, OSHA, the Food and Drug Administration, the Consumer Product Safety Commission, and the Department of Agriculture. The current agenda of the IRMC includes: cancer risk assessment guidelines development; reproductive effects risk assessment guidelines development; and coordinated strategy development for formaldehyde and halogenated solvents.

7. Does the Office of Management and Budget ("OMB") ever comment upon or review agency risk assessment at any time during the risk assessment process? If so, at what point(s) in the risk assessment process does such OMB comment or review occur? Are any records of such comments or reviews made by the agency, and if so, are they made available to the public or the scientific community? Under what legal authority does OMB comment upon or review agency risk assessment? What is the effect of an OMB comment on or review of an agency risk assessment?

   Response: OMB reviews the Agency's proposed and final rules under the authority of Executive Order 12291. During the course of that review, OMB sometimes raises questions or offers comments concerning OSHA's quantitative risk assessments in order to carry out its responsibilities under the Executive Order. Many of OMB's comments or questions on the risk assessments are made or asked orally, and OSHA frequently responds to OMB in the same manner. The Agency takes these comments into consideration as appropriate in further developing a proposed or final rule. For example, OMB raised a number of questions concerning OSHA's risk assessment for its ethylene dibromide proposal. OSHA answered OMB's questions about risk assessment informally, but did not include these questions or the Agency's responses to them in the record since their purpose was apparently to educate OMB staff on technical issues associated with the risk assessments. Questions from OMB on other significant issues in the standard were included in the record.

8. Provide any written documents which refer to any procedures or understanding by which OMB comments upon or reviews agency risk assessments. Provide, for the ten risk assessments most recently completed, all written documents which make any reference to any comment, review

or contact by anyone at OMB with respect to such risk assessments.

OSHA has no documents that refer to any procedures or understanding by which OMB comments upon or reviews the Agency's risk assessments, except, of course, Executive Order 12291, a copy of which is attached. (Attachment 1) As noted in the answer to question 7 above, OMB's queries and OSHA's responses on risk assessment have been largely oral. We have searched our files and are providing you with the documents that we have which make reference to questions received from OMB concerning OSHA's risk assessments. (Attachment 2)

9. Please indicate whether the answers to these questions have in any way been reviewed by, or commented upon, by anyone at OMB.

Response: Submissions to Congressional Committees are routinely coordinated and cleared through the Solicitor of the Department of Labor (DOL), particularly when other Federal agencies are involved. The DOL Solicitor clears such documents first with other agencies within DOL and then with the Office of Management and Budget, which in turn clears the document with other relevant Departments and agencies of the Executive Branch. This procedure, which has been followed by past administrations as well as by the present one, permits the orderly exercise of government by the Executive Branch.

10. Indicate the extent to which the agency may be legally required to conduct a risk assessment, or otherwise consider risk or costs of proposed agency action, and indicate the legal authority for such requirements, whether by statute, court decision, executive order, or other authority.

Response: Section 3(8) of the Occupational Safety and Health Act of 1970 defines an occupational safety and health standard as a standard that is "reasonably necessary or appropriate to provide safe or healthful employment." Section 6(b)(5) of the Act requires OSHA to consider the feasibility of its standards for toxic materials or harmful physical agents. The Act has been interpreted by the courts to require OSHA to consider the economic feasibility of its standards. This includes the costs of its regulations.

On July 2, 1980, the United States Supreme Court, in Industrial Union Department, AFL-CIO v. American Petroleum Institute et al., ruled that section 3(8) requires that in regulating toxic substances OSHA must find that the substance in question poses a significant health risk in the workplace. The court further stated:

> It is the Agency's responsibility to determine, a "significant" risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2 percent benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it.

OSHA has interpreted the benzene decision to mean that risk assessment must be done, when possible, on standards issued under Section 6(b)(5).

Other statutes require OSHA to consider the costs of its regulatory actions. For instance, the Regulatory Flexibility Act of 1980 requires agencies to prepare regulatory flexibility analyses to accompany rules that will have a significant economic impact on a substantial number of small entities. The purpose of the analyses is to consider alternatives that could lessen any such impact. Similarly, the Paperwork Reduction Act of 1980 requires federal agencies to analyze their existing and proposed information collection requirements to ensure that such requirements do not impose unnecessary recordkeeping and reporting burdens on the public.

SEP 27 1983

MEMORANDUM FOR: GARY STROBEL
Special Assistant

FROM: STEPHEN MALLINGER
Deputy Director
Directorate of Technical Support

SUBJECT: OMB Comments on the Proposed EDB Standard

All the members of the EDB team have reviewed OMB's major comments and we have come to the conclusion that the proposal and Regulatory Impact Assessment should remain as it is now and the proposed standard should be published in the Federal Register as soon as possible. The following items go over all the comments the representatives from OMB addressed to us at our September 22, 1983 meeting:

1.a. Comment:

The standard requires X-rays for employees every year. If workers are exposed to low levels wouldn't this be a greater hazard.

Answer:

The standard requires X-rays only for individuals who have to wear a respirator and only at a frequency of once every five years. The X-ray is part of a pulmonary function examination and the agency's physicians of the Office of Occupational Medicine believe that X-rays are an essential part of this examination. Also, the standard does allow the employer to use previous X-rays of employees if they are within the five year time period.

Attached is a copy of several tables from the text "The Effects on Populations Exposure to Low Levels of Ionizing Radiation: 1980." The first table indicates the mean dose in mrads from chest X-rays. The second table indicates the number of excess deaths per million, average value per rad. To express this value in another way it is

568 excess deaths/1,000,000 persons exposed/rad/year.

To convert this number to the excess number of deaths resulting from a chest X-ray (10 mrads) every five years takes the following steps:

1. 568/1,000,000/1 rad/year
2. 114/1,000,000/1 rad/5 years (as required in proposed std)
3. $\frac{45\ \text{years}}{70\ \text{years}}$ (114/1,000,000/1 rad) adjust for the working lifetime
4. 81/1,000,000/1 rad (.09 rads exposure) (9 X-rays over 45 years x 10 mrads)
5. 7.3/1,000,000 excess deaths

or

6. 0.0073/1000 excess deaths.

Clearly this number is well below the .2 to 6/1000 excess deaths from exposure to EDB at 0.1 ppm.

Z.a. Comment:

The protective equipment section should be changed to drop the requirement that only 8-hour resistant clothing that can be used where employees may be exposed to a splash or spill. Industry should be allowed to decide on the type of equipment.

Answer:

EDB penetrates many materials used in the manufacture of protective gloves and suits. The break through time for many of these materials is in minutes. EDB is very caustic and damaging to the skin even with very brief contact. Allowing employers to substitute protective clothing that has less resistance and break through occurs in less than 8-hours is less protective. For example, an employee may have some EDB that came in contact with this protective clothing in the morning but may not be aware of the problem and not remove the clothing until the end of shift or until a serious problem starts to occur. The proposal was written to fully protect these employees for the entire shift and at the end of that time the equipment would be removed. The 8-hour resistant clothing may be more cost effective. At least four materials meet this requirement and they are:

1. 568/1,000,000/1 rad/year
2. 114/1,000,000/1 rad/5 years (as required in proposed std)
3. $\frac{\text{45 years}}{\text{70 years}}$ (114/1,000,000/1 rad) adjust for the working lifetime
4. 81/1,000,000/1 rad (.09 rads exposure) (9 X-rays over 45 years x 10 mrads)
5. 7.3/1,000,000 excess deaths

or

6. 0.0073/1000 excess deaths.

Clearly this number is well below the .2 to 6/1000 excess deaths from exposure to EDB at 0.1 ppm.

7.a. Comment:

The protective equipment section should be changed to drop the requirement that only 8-hour resistant clothing that can be used where employees may be exposed to a splash or spill. Industry should be allowed to decide on the type of equipment.

Answer:

EDB penetrates many materials used in the manufacture of protective gloves and suits. The break through time for many of these materials is in minutes. EDB is very caustic and damaging to the skin even with very brief contact. Allowing employers to substitute protective clothing that has less resistance and break through occurs in less than 8-hours is less protective. For example, an employee may have some EDB that came in contact with this protective clothing in the morning but may not be aware of the problem and not remove the clothing until the end of shift or until a serious problem starts to occur. The proposal was written to fully protect these employees for the entire shift and at the end of that time the equipment would be removed. The 8-hour resistant clothing may be more cost effective. At least four materials meet this requirement and they are:

Material	Mfg.	Resistance
1. Polyvinyl alcohol	Edmont	Greater than 8 hr.
2. Vitril	Surety Rubber	Greater than 8 hr.
3. Vitrile	Norton	Greater than 16 hr.
4. Vitron	Norton	Greater than 8 hr.

3.a. Comment:

The Regulatory Impact Analysis greatly underestimates the cost of the medical surveillance program.

Answer:

After reviewing the costs estimated for medical surveillance, the team believes the entire cost estimated for this requirement is within the "ballpark." This cost assumes that many of the current users, such as small grain elevators, will switch to other available liquid alternatives and no longer falls under the standard. A recent Centaur report confirms these findings. In addition, Dr. Terpeluk confirmed that the price estimates quoted for the individual physical examinations are realistic and close to what occupational clinics charge in Baltimore.

4.a. Comment:

It is not clear that the proposal only requires X-rays as part of the pulmonary function evaluation to determine that a worker is capable of safely wearing a respirator.

Answer:

The medical surveillance provisions of the proposal clearly requires chest X-rays "initially and at five year intervals...if an employee is to wear a respirator..." (paragraph (m)(2)(v); emphasis added).

In addition to the clear regulatory language in the proposal, Appendix C entitled Medical Surveillance Guidelines for Ethylene Dibromide states that as part of the medical surveillance program the physician must assess the pulmonary status of each employee who must wear a respirator and that this assessment must include a chest X-ray initially and at least every five years (see page 243). Statements showing similar corroborative intent can also be found in Appendix B (page 237) and on pages 154 and 164 in the summary and explanation of the standard section. Nothing in the document suggests or implies that all employees placed in the medical surveillance program will be subjected to X-rays; instead everytime X-rays are discussed, they are always in conjunction with determining whether an employee can safely wear a respirator. Since the document is clear on this point, we see no reason to change it at this time. If after public comment and hearing it appears that there is some confusion on this point, we will make whatever changes appear appropriate.

5.a. Comment

The labeling requirement for the proposal is too broad and will be very expensive for industries to follow. This is because the definition of container includes everything including reaction vessels, holding tanks and pipes.

Answer

The definition section of the regulatory language does not specifically include pipes or piping systems. Rather it includes "reaction vessels, storage tanks and blending tanks." The "warning statements" section included in the proposed standard was not meant to include pipes. Since the agency does not control labeling of pesticide containers, the warning requirements would not apply to those industries where EDB is used as a pesticide. Therefore, the warning statement section of the standard only applies for the most part to other industries. There are three manufacturing plants, 4 antiknock blending facilities, 20 formulation plants and a small section of oil refineries. This small number of facilities greatly reduces the costs associated with this section of the standard. The team strongly feels warning statements are an essential part of employee information and training.

6.a. Comment

The proposal should make clear that in the final standard the methods of the compliance section will be consistent with the ANPR (48 FR 7473) relating to whether OSHA should allow greater reliance on respirators.

The discussion of the ANPR is not given proper emphasis in that it is "buried" in the back of the methods of compliance discussion.

Answer:

The proposal provides that feasible engineering and work practice controls must be used to reduce exposure to within the PEL except in certain limited circumstances such as when exposures are intermittent in nature and short term. This proposal was specifically tailored to conditions of exposure which may be unique to employee exposure to EDB in industry. The ANPR relating to compliance priorities is still in a developmental stage. When the responsive comments to the ANPR are evaluated and a proposal is prepared, OSHA can then determine whether EDB should be included within the scope of that proposal or whether there are factors peculiar to EDB that indicate that the method of compliance section of EDB should not be consistent with a general method of compliance policy.

The discussion of the ANPR (48 FR 7473) was not "buried" in the method of compliance discussion. OSHA is extremely interested in receiving comments on this issue in this proceeding. Accordingly, it placed the discussion and solicitation of comments on the issue toward the end of the discussion of the subject. It should be noted that throughout the document requests for comment appear towards the end of the various sections and to change the placement in this section might have the unintended result of OSHA receiving fewer rather than more comments on this important issue.

7.a. Comment:

OMB expressed concern over risk estimates derived from a negative epidemiology study.

Answer:

Comments on page 79 address the results of an EPA-CAG risk assessment based on the epidemiology study of Ott et al. (1977). The risk assessment was performed in 1978, before the results of the NCI bioassay were available.

Using a one-hit model, CAG reported the risk from EDB exposure to be:

$$P = 1 - e^{-171x},$$

where x is the measure of dose. In order to compare the results of this assessment with those of other risk assessments submitted to the record, OSHA used this equation to compute the risk for a lifetime working exposure to EDB at 100 ppb. That calculation is reported in the proposal.

OSHA's best estimate of risk was based on the Brown risk assessment; the results of the CAG risk assessment were reported for completeness.

8.a. Comment:

OMB asked if the confidence limits referred to on page 46 were 90 percent limits (as stated) or 95 percent limits.

Answer:

These confidence limits were reported by Levine as 90 percent confidence limits.

Attachment

bcc: Auchter, Mallinger, Sherman, Yurachek, Adams via EM
OSHA/DTS/SMallinger/gi 9/27/83

TELEPHONE - MEETING LOG

SUBJECT ETO Risk Assessment

PREPARED BY Yurachek DATE 8/5/83

MEETING INCOMING CALLS ✓

OUTGOING CALLS

PERSON(S)	ORGANIZATIONS(S)	TELE. NO
Sam Baghdady	OMB	395-3097

OBJECTIVE:

SUMMARY:

He called to ask ~~the~~ about Table VI in the Preliminary QRA, specifically the source of one set of numbers.

FOLLOW-UP PROCEDURES

SPECIAL NOTES:

cc Beliles

The Effects on Populations of Exposure to Low Levels of Ionizing Radiation: 1980

TABLE III-5 Mean Active Bone Marrow Dose to the Adult Population from Medical and Dental X-Ray Procedures, 1970[a]

Examination	Mean Dose to Total Red Marrow per Examination, mrads[b]	Annual per Capita Examination Rate[b]		Annual per Capita Dose, mrads ± SE
Head and neck				
Skull	78	0.020		1.6 ± 0.1
Cervical spine	52	0.022		1.2 ± 0.2
Other	—	—		0.6 ± 0.2
Thorax				
Chest, photofluoro.	44	0.073		3.2 ± 0.3
Chest, radiographic	10	0.306		3.2 ± 0.1
Thoracic spine	247	0.010		2.5 ± 0.4
Ribs	143	0.009		1.3 ± 0.2
Other	—	—		1.9 ± 0.4
Upper abdomen				
Upper GI series	535			24.3 ± 4.7
Radiographic	294	0.046	13.5 ± 4.3	
Fluoroscopic	241	0.045	10.8 ± 1.9	
Scan	167			
Spot film	74			
Lumbar spine	347	0.023		8.1 ± 0.6
Gall bladder	168			3.7 ± 0.4
Radiographic	129	0.027	3.5 ± 0.3	
Fluoroscopic	39	0.006	0.2 ± 0.3	
Scan	29			
Spot film	10			
Small bowel series	422	0.002		1.0 ± 0.3
Other	—	—		2.1 ± 1.0
Lower abdomen				
Barium enema	875			21.2 ± 1.8
Radiographic	497	0.024	11.9 ± 1.0	
Fluoroscopic	378	0.024	9.3 ± 1.5	
Scan	268			
Spot film	110			
IVP	420	0.024		10.1 ± 0.6
Lumbosacral spine	450	0.013		5.7 ± 0.7
Abdomen (kidneys, ureters, and bladder)	147	0.020		2.9 ± 0.4
Other	—	—		0.4 ± 0.2
Pelvis				
Pelvimetry	595	0.002		1.4 ± 0.5
Pelvis	93	0.012		1.1 ± 0.2
Hip	72	0.009		0.7 ± 0.1
Other	—	—		1.2 ± 0.7
Extremities				
Femur	21	0.002		0.04 ± 0.02
Dental	9.4	0.312		2.9 ± 0.2
			TOTAL:	103 ± 5

[a] Data from Shleien *et al.*[13]

[b] Values have been independently rounded.

TABLE V-4 Comparative Estimates of the Lifetime Risk of Cancer Mortality Induced by Low-LET Radiation—Excess Deaths per Million, Average Value per Rad by Projection Model, Dose-Response Model, and Type of Exposure

		Projection Model			
		Single Exposure to 10 Rads		Continuous Lifetime Exposure to 1 Rad/Yr	
Source of Estimate	Dose-Response Models[a]	Absolute	Relative	Absolute	Relative
BEIR, 1980[b]	LQ-L, $\overline{LQ\text{-}L}$	77	226	67	169
1972 BEIR report factors[c]	Linear	117	621	115	568
UNSCEAR 1977[d]	Linear	75-175			

[a] For BEIR 1980, the first model is used for leukemia, the second for other forms of cancer. The corresponding estimates when the other models are used (thereby providing an envelope of risk estimates) are:

L-L, $\overline{L\text{-}L}$	167	501	158	403
Q-L, $\overline{Q\text{-}L}$	10	28		

[b] The values are average values per rad, and are not to be taken as estimates at only 1 rad of dose.

[c] 1972 BEIR[56] postnatal, age-specific risk factors used with 1969-1971 life tables, with plateau extending throughout the lifetime remaining after irradiation, estimate (b) in the 1972 report. The average age of the 1969-1971 life-table population exceeds that of the 1967 U.S. population used for the 1972 BEIR report. For this reason, the numbers shown here for continuous exposure are larger, on a per-rad basis, than those obtainable from Tables 3-3 and 3-4 of the 1972 BEIR report.

[d] UNSCEAR range of estimates for low-dose, low-LET radiation (p. 414, para. 318).[62]

cancer deaths per million persons exposed per rad, compared with 568 in the 1972 BEIR report, and the absolute-risk projection is 67 deaths, compared with 115. Although the present report uses much information not available for the earlier report, the differences mainly reflect differences in the assumptions made by the two Committees. The present Committee preferred a constrained linear-quadratic, rather than the linear, dose-response model for low-LET radiation and preferred not to assume a fixed relationship between the effects of high- and low-LET radiation. There is an additional difference between the two reports with respect to the relative-risk projections: the present estimates do not, as in the 1972 report, carry through to the end of life very high relative-risk coefficients obtained with respect to childhood cancers induced by radiation; this accounts for about half the magnitude of the 1972 rela-

1. Question on the medical surveillance section.

Annual physicals are required if an employee is exposed to EDB above the aciton level (50 ppb) for 30 or more days per year; or if an employee is required to wear a respirator.

The trigger of 30 days was used as a cut-off to lessen the medical surveillance burden on employers yet still provide adequate employee protection.

Employees who may not be exposed more than 30 days but who are required to wear a respirator because there is potential for exposure above the PEL or have dermal contact (i.e., maitenance personnel) are therefore afforded adequate protection as well.

All employees who receive physicals must have the required blood tests. EDB is a potent toxin that causes delayed acute affects on the liver and kidney. These tests are specifically required and designed to determine if there is or has been any change in the function of these organ systems.

Only employees who are required to wear a respirator receive a pulmonary function test each year and a chest x-ray every five years as part of the medical surveillance program - References to this question are on pages 165, 166, 167 of the final version of the EDB proposal.

2. Question on warning statements (labelling).

The standard states that... warning statments are to appear on all containers in the workplace. Reference page 197.

The standard's definition of a container is "any receptical in which EDB or a liquid containing EDB is placed or kept including reactor vessels, storage tanks and blending tanks." Reference page 179.

The words "placed" and "kept" could lead someone to assume that pipes must be labeled. However, this was never intended. There is no sentence, however, in the proposal which specifically says that that was not intended.

3. Question on the preference for use of engineering controls.

The use of engineering controls is only required for those industries which have operations which use EDB more than 30 days per year and accounts for only 15% of the total compliance costs of the proposal.

The reliance on engineering controls to control EDB exposure in these industries is necessary because of EDB's extremely toxic properties; most importantly, its ability to readily penetrate the skin.

Materials which are commonly used to make personal protective equipment are also as easily penetrated by EDB and therefore do not provide adequate exposure protection.

4. Question on the risk assessment section.

In response to the ANPR, OSHA received a number of risk assessments. The EPA-CAG assessment was one of them. The inclusion of the CAG assessment in the proposal constitutes a complete discussion of the range of risk which has been estimated for EDB exposure. The CAG risk assessments are public documents and omitting them from the discussion would have been negligent. In addition, the level of risk predicted by CAG was not unique: predictions of risk as high (990/1000) were made by SRI International for NIOSH and CAL/OSHA.

A discussion of the CAG risk assessment in the proposal does not constitute endorsement of its methodology. In fact, OSHA explicitly states that we have endorsed "Dr. Brown's approach to the quantitative assessment of risk from exposure to EDB" (70-725 excess deaths/1000 workers). The specific reasons for this selection are given in the document (pp. 90-92). It should be noted that OSHA has not adopted the most conservative estimates of risk, but has endorsed estimates which are mid-range and which overlap with those from other assessments.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

June 1, 1984

The Chairman

The Honorable James H. Scheuer
Chairman
Subcommittee on Natural Resources,
  Agriculture Research and Environment
Committee on Science and Technology
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

I am pleased to provide answers to the questions in your letter of April 23, 1984, concerning H.R. 4192, the "Risk Assessment Research and Demonstration Act of 1983." As in our earlier comments dated January 9, 1984, and consistent with the Bill itself, our answers place particular emphasis upon risk analysis involving issues of chronic health hazards.

In accordance with your request, we are considering "risk assessment" to include both "risk analysis - the process of quantification, as much as possible, of the probabilities of an identified risk" and "risk evaluation-the process of judging the acceptability of various levels of risk to individuals, society or the environment." The questions and their answers follow:

1. QUESTION - List and briefly describe, all uses of risk assessment within the agency.

The assessment of risk is used within the Commission in two ways. First, it is used to provide certain findings which are required by two of the acts which the Commission administers prior to actions to ban, set a standard, or require a label for a consumer product. These acts are the Consumer Product Safety Act and the Federal Hazardous Substances Act. Second, it is used along with other considerations in an abbreviated form to select hazards for priority attention from among the universe of consumer products. Specifically, the Commission considers the following factors in setting priorities: frequency and severity of injuries; causes of these injuries; the relative costs and consumer benefits of Commission actions; the vulnerability of those likely to be injured; the possibility of chronic illness or future injuries; and the probability of exposure.

2. QUESTION - Indicate the total number of "risk assessments" completed and in progress during the last twelve months. For such "risk assessments," indicate the total cost to the agency, including separate figures for staff resources and consultant or contractual expenses incurred.

During the last twelve months, the Commission has completed risk analyses on three chemicals found in consumer products: di(2-ethylhexyl)phthalate (DEHP), asbestos and formaldehyde. In addition, it has worked on a number of other chemical evaluations, primarily to assist in priority setting or to determine the usefulness of data on a particular chemical for risk analysis. The staff resources and consultant or contractual expenses incurred to date are:

	Chemical	Professional Staff Months	Contract $ (In thousands)
(a)	DEHP	32	187
(b)	Formaldehyde	136	335
(c)	Asbestos	83	85
(d)	Other	92	264
	Total	343	871

These risk analyses have been used by the Commission to support various actions, as appropriate.

3. QUESTION - Indicate the extent to which risk assessments conducted by the agency include the elements set out in Sec. 107(a) of Title I of H.R. 4192.

As a general practice, the Commission's risk assessments include the elements defined in Sections 107(a)(1) through 107(a)(6). With regard to Section 107(a)(7), significant new information is always considered and revised risk analyses may be made and forwarded to the Commissioners for their consideration. The elements of Section 107(a)(8) are not included within the particular assessment, but the Commission has performed comparative risk analyses for in-house evaluation purposes. When data are available, elements of Section 107(a)(9) are included for the purpose of identifying high risk populations and equitable sharing of risks and benefits.

In addition, it should be noted that the Commission is required by Section 28(b) of the Consumer Product Safety Act to convene a Chronic Hazard Advisory Panel (CHAP) selected from a list of nominees provided by the National Academy of Sciences. This panel advises the Commission concerning the chronic hazards of cancer, birth defects, and gene mutations associated with chemical(s) in the consumer product under study under 15 U.S.C. 2077, 2080(b). The Commission is precluded from any regulatory action, including an Advance Notice of Proposed Rulemaking, until the CHAP has submitted its report. If feasible, the panel's report shall include an estimate of the probable harm to human health that will result from exposure to the substance.

4. QUESTION - Indicate the extent to which the agency makes its risk assessments, and any guidelines under which risk assessments are prepared, available to the public or to the scientific community.

The Commission makes its risk assessments routinely available to the public and the scientific community. The affected industry and consumers are asked to comment on such assessments. Chronic Hazard Advisory Panels (see above) are asked to review the factors considered in such assessments. The CPSC has not developed its own guidelines for risk assessment, but has joined other Federal health and safety research and regulatory agencies in the development of guidelines and principles for carcinogen risk assessment. These are routinely submitted for expert peer review and public comment. Examples include the Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks which was issued jointly by the CPSC, EPA, FDA and OSHA, and the soon to be published Chemical Carcinogens: A Review of the Science and Its Associated Principles which has been drafted at the request of the Office of Science and Technology Policy by senior scientists from ten Federal organizations, including the CPSC.

5. QUESTION - Describe any efforts the agency has made within the last two years to improve or expand the use of risk assessment within the agency, including any efforts to improve intra-agency coordination of risk assessments or the development of any guidelines or protocols for risk assessments.

During the last two years the Commission has initiated activities to improve and expand the use of risk assessment within the agency. A risk analysis document review group has been created to provide interdisciplinary in-house peer review. Working with other Federal agencies the Commission has acquired and utilized the computer models commonly used for quantitative risk assessments. This has resulted in the routine presentation of the full spectrum of results using different quantitative risk assessment models. Finally, agency staff routinely keep abreast of the latest developments in the field through literature review and extensive interagency contacts. Risk assessment methodology is improved and expanded accordingly.

6. QUESTION - Describe any efforts the agency makes to coordinate its risk assessments or its risk assessment procedures with other federal agencies.

The Commission for many years has worked closely with other Federal agencies to coordinate its risk assessments and risk assessment procedures. At this time, the Commission staff is participating in the activities of various interagency groups concerned with risk assessments including: (1) the Federal Asbestos Task Force; (2) the Interagency Committee on Indoor Air Quality; (3) the Interagency Risk Management Council which is focusing on formaldehyde and risk assessment inference guidelines, (4) the Interagency Toxic Substances Data Committee, which is presently sharing information on how exposure assessments are conducted and; (5) the Interagency Staff Group (ten Federal organizations) developing cancer principles (see also our response to Question 4 above).

7. QUESTION - Does the Office of Management and Budget ("OMB") ever comment upon or review agency risk assessments at any time during the risk assessment process? If so, at what point(s) in the risk assessment process does such OMB comment or review occur? Are any records of such comments or reviews made by the agency, and if so, are they made available to the public or the scientific community? Under what legal authority does OMB comment upon or review agency risk assessments? What is the effect of an OMB comment on or review of an agency risk assessment?

The Office of Management and Budget (OMB) does not comment upon CPSC risk assessments at any time during the risk assessment process.

8. QUESTION - Provide any written documents which refer to any procedures or understanding by which OMB comments upon or reviews agency risk assessments. Provide, for the ten risk assessments most recently completed, all written documents which make any reference to any comment, review, or contact by anyone at OMB with respect to such risk assessment.

Since OMB does not comment on CPSC risk assessments, there are no written documents.

9. QUESTION - Please indicate whether the answers to these questions have in any way been reviewed by, or commented upon, by anyone at OMB.

The answers to these questions have not been reviewed by, or commented upon, by anyone at OMB.

10. QUESTION - Indicate the extent to which the agency may be legally required to conduct a risk assessment, or otherwise consider risks or costs of proposed agency action, and indicate the legal authority for such requirement, whether by statute, court decision, executive order, or other authority.

The major substantive rulemaking provisions of several of the statutes administered by the Commission require the Commission to provide information in a regulatory analysis that includes "a description of the potential benefits and potential costs of the rules, including costs and benefits that cannot be quantified in monetary terms, and the identification of those likely to receive the benefits and bear the costs." 15 U.S.C. 1193 (j)(1)(A), 15 U.S.C. 1262(i)(1)(A), and 15 U.S.C. 2058(f)(2)(A). Moreover, in order to promulgate a rule, the statutes require the Commission to find, among other things, that "the benefits expected from the rule bear a reasonable relationship to its costs". 15 U.S.C 1193(j)(2)(B), 15 U.S.C. 1262 (i)(2)(B), and 15 U.S.C. 2058(f)(3)(E). Therefore, it is apparant that in estimating the benefits (risk reduction) of a rule the Commission is issuing, it must also assess the risks presented by the product being regulated. Court decisions interpreting the phrase "unreasonable risk of injury," as it is used in the Commission's statutes, have also indicated that in issuing rules the Commission must assess the risks of the product being regulated and show that the benefits of the regulation bear a reasonable relationship to its costs.

Thank you for giving us the opportunity to provide additional information on this proposed legislation. Please let me know if we can be of further help.

Sincerely,

Nancy Harvey Steorts
Chairman

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUN 1

The Honorable James H. Scheuer
Chairman, Subcommittee on Natural Resoures,
  Agriculture Research and Environment
Committee on Science and Technology
House of Representatives
Washington, D. C. 20515

Dear Mr. Scheuer:

This is in response to your letter of April 23 concerning Title I of H.R. 4192, the Risk Assessment Research and Demonstration Act of 1983.

In your letter, you have asked several questions about how the Food and Drug Administration (FDA) applies risk assessment in making regulatory decisions concerning potentially harmful substances. We understand your questions concern the use of the type of risk assessment defined in the proposed bill: a formal process that focuses on (1) the quantification of the potential risk resulting from chronic exposure to a substance, and (2) the determination of the acceptability of risk to the public.

Enclosed are detailed answers to your questions prepared by the FDA. If I can be of further assistance, please let me know.

Sincerely,

Margaret M. Heckler

Margaret M. Heckler
Secretary

Enclosure

REPORT FROM THE SECRETARY TO THE HONORABLE JAMES H. SCHEUER IN RESPONSE TO RISK ASSESSMENT QUESTIONS ADDRESSED TO THE FOOD AND DRUG ADMINISTRATION

Question 1. List, and briefly describe, all uses of risk assessment within the agency.

Answer. Most of FDA's decisions concerning the safety of regulated products are made on the basis of semi-quantitative risk assessments and not on formal quantitative risk assessments as contemplated by the bill. The statutory standards for showing the safety of drugs, devices, biologicals, food additives, food contaminants, and other products or substances differ, and most of these standards can be appropriately met through semi-quantitative risk assessments.

The situation in which FDA most frequently employs formal quantitative risk assessment procedures, as envisioned in H.R. 4192, is for decisions on added carcinogenic substances in food in cases where the Delaney anti-cancer clause is inapplicable. The Federal Food, Drug, and Cosmetic (FD&C) Act contains three separate anti-cancer clauses that are collectively referred to as the Delaney clause. These provisions prohibit the FDA from approving food additives, color additives, and new animal drugs that induce cancer in man or animals. But, under an exception known as the DES proviso, carcinogenic substances may be used in food-producing animals if no residues in edible tissues can be detected by a method approved by the Secretary.

Since the enactment of the DES exemption in the early 1960's, rapid advances in science have permitted the measurement of smaller and smaller amounts of residues in foods. With today's sophisticated analytical chemical methodologies, we can now detect residues of compounds at concentrations as low as parts per billion and parts per trillion. For certain chemicals, residues at these concentrations may not, in fact, pose any significant risk of cancer to humans. Therefore, FDA has interpreted the DES exemption as allowing FDA to develop techniques to establish procedures and criteria for approving acceptable concentrations of carcinogenic residues in edible products of food-producing animals that have been treated with drugs, food additives, or color additives. These procedures and criteria are commonly referred to as the "SOM" ("sensitivity of the method") and were proposed as regulations (44 FR 17070, March 20, 1979). In our proposal we announced that these procedures would be informally implemented as guidelines pending the promulgation of any final rule resulting from the proposal.

The SOM calls for quantitative estimation of the risk of cancer presented by the residues of any carcinogenic compound proposed for use in food-producing animals. The SOM proposes that before FDA may approve a carcinogenic compound for use in food-producing animals, an analytical method must be available that can accurately and dependably measure the carcinogenic residues of the compound at concentrations greater than those estimated to be insignificant through risk assessment procedures. (Hence the name "sensitivity of the method".)

Another example of FDA's application of formal quantitative risk assessment is its "constituents policy," announced in an advance notice of proposed rulemaking, published on April 2, 1982 (47 FR 14138). Under this policy, FDA allows the marketing of a noncarcinogenic food additive or color additive that contains a carcinogenic constituent provided that the constituent is present in a concentration that presents an appropriately low level of estimated risk. A central feature of this policy is that the additive itself must not be carcinogenic. Otherwise the proscriptions of the Delaney clause would apply and there would be no need for formal estimation of the degree of risk presented by the carcinogenic additive. The constituents policy was upheld in Scott v. FDA, Nos. 82-3544/3759 (6th Cir., Feb. 23, 1984)(copy attached).

FDA has also used formal quantitative risk assessment procedures to assist its efforts to establish tolerances and action levels concerning unavoidable contaminants in food regulated under section 406 of the FD&C Act (e.g., dioxins in Great Lakes fish). Section 406 allows FDA to consider not only the toxicity of the unavoidable food contaminant but also the value of the food and the extent to which the occurrence of contamination can be controlled. This section is unique in the statutory scheme concerning the regulation of toxins in food.

FDA makes safety decisions on a wide variety of products, including medical devices, animal and human drugs, foods, cosmetics, and vaccines. Different statutory provisions and burdens of proof apply to the demonstration of the safety of a given product. In making safety decisions, FDA, by necessity, often relies on criteria and procedures common to formal quantitative risk assessments. This approach results in a demonstration of the safety or lack of safety of a regulated product. FDA may perform a formal quantitative risk assessment when the agency believes it needs to characterize more fully the risk presented by the product. Examples of this use of risk assessment include ongoing consideration of the risks presented by ethylene oxide (widely used as a sterilant for medical devices) and radiation exposure (from medical applications and certain consumer products).

Question 2. Indicate the total number of "risk assessments" completed and in progress during the last 12 months. For such "risk assessments," indicate the total cost to the agency, including separate figures for staff resources and consultant or contractual expenses incurred.

Answer. For your convenience we have tabulated our response to this question as follows:

ITEM	APPLICABLE STATUTORY AUTHORITY	PERSONYEARS	DOLLARS	
			IN HOUSE	CONTRACT
Constituents of food additives and color additives	§§409 and 706 FD&C Act (food and color additives)	4.0	200,000	0
Dioxin	§406 FD&C Act (unavoidable contaminants)	2.0	100,000	0
Furazolidone	§512 FD&C Act (new animal drugs)	0.6	30,000	0
Ethylene Oxide on Devices	§501 FD&C Act (adulterated devices)	6.0	300,000	0
Radiation Exposure	§263d Radiation Control for Health & Safety Act (radiation-emitting medical and consumer products)	4.0	200,000	0
Total - 5		16.6	830,000	0

Question 3. Indicate the extent to which risk assessments conducted by the agency include the elements set out in section 107(a) of Title I of H.R. 4192.

Answer. The extent to which FDA can apply the elements set out in section 107(a) of the bill varies depending upon the statutory standards involved. [Sec. 107(a)(5).] For example, under sections 706 (color additives), 409 (food additives) and 512 (animal drugs) of the FD&C Act, FDA may not compare risks [Sec. 107(1)], make tradeoffs [Sec. 107(a)(6)], consider other risks unrelated to the specific regulated substance [Sec. 107(a)(8)], or attempt to distribute "risks" and "benefits" more "equitably" [Sec. 107(9)]. Under Sec. 406 of the Act, however, FDA may consider not only the toxicity of an "unavoidable" contaminant in food but also the value of the food and the extent to which the occurrence of the contaminant can be controlled. [Sec. 107(a)(1) and (6).]

The provisions in the FD&C Act pertaining to the safety of drugs, devices and radiation differ from those for foods in many ways. In particular they provide for risk/benefit balancing. [Sec. 107(a)(1) and (6).] But even here the benefits are limited to health benefits or off-setting risks from possible side effects. FDA may not balance risks to human life with the economic and social consequences of approving or not approving the products it regulates.

In all its risk assessments, whether formal quantitative assessments or semi-quantitative assessments, FDA tries to be as explicit as possible regarding the identification of the specific assumptions and uncertainties underlying its decisions. [Sec. 107(a)(4).] FDA regards the separation between scientific and policy judgments as vital to sound decisionmaking and pays special attention to the institutional separation of internal scientific and policy groups. [Sec. 107(a)(2).]

Question 4. Indicate the extent to which the agency makes its risk assessments, and any guidelines under which risk assessments are prepared, available to the public or to the scientific community.

Answer. Information and guiding principles pertaining to a risk assessment are available to the public. For example, as in the case of the SOM and the constituents policy, FDA not only has provided, but has offered for public comment, the procedures or basic principles it follows in conducting a risk assessment. However, FDA may not make publicly available a risk assessment that would disclose data to which the FD&C Act affords confidential status unless the owner of the data concurs.

Question 5. Describe any efforts the Agency has made within the last two years to improve or expand the use of risk assessment within the Agency, including any efforts to improve intra-agency coordination of risk assessments or the development of any guidelines or protocols for risk assessments.

Answer. The most significant set of procedures and criteria utilized by FDA to improve and expand the use of quantitative risk assessment within FDA are in the "constituents policy," and in the SOM. Other illustrations of FDA's efforts to improve intra-agency coordination of risk assessments pertain to the FDA's Center for Food Safety and Applied Nutrition's (CFSAN)/Risk Assessment Committee. This internal committee is a standing body that reviews CFSAN's risk assessment activities. CFSAN also has offered a training course in Risk Assessment, a seminar series that was presented to staff members involved in risk assessment.

In addition, FDA recently chartered an intra-agency task force on developmental toxicology. This task force will prepare uniform principles for the evaluation of studies concerning the reproductive toxicity of regulated substances which will contribute to the performance of Agency risk assessments.

Question 6. Describe any efforts the agency makes to coordinate its risk assessments or its risk assessment procedures with other Federal agencies.

Answer. When a compound is of common interest to FDA and one or more other agencies, FDA routinely shares its risk assessments with the other agencies. For example, the unavoidable food contaminant dioxin presented a regulatory situation of concern to three agencies: FDA (food contamination), EPA (water contamination), and CDC (soil contamination). Scientists from the three agencies met several times to define and eliminate, where possible, the differences in their agencies' approaches to risk assessment.

Because of its interest in formal quantitative risk assessment as well as less formal types of risk assessment, FDA has been actively involved in efforts with other agencies to share information concerning risk assessment procedures and to attempt to devise uniform procedures and criteria. A sampling of these efforts is listed below.

- FDA is a member of the Interagency Risk Management Council (IRMC) - an assembly of the agency chiefs of the Environmental Protection Agency (EPA), the United States Department of Agriculture (USDA), the Consumer Product Safety Commission (CPSC), the Occupational Safety and Health Administration (OSHA) and the FDA. The Council has been formed to coordinate risk assessment activities. FDA and the National Cancer Institute cochair a subcommittee of the Council that is to develop guidelines for assessing carcinogenic risks.

- FDA participated with EPA in an effort to focus on the risks arising from diagnostic radiation exposure.

- FDA chaired an interagency conference for evaluating the risks of exposure to formaldehyde at the request of the Office of Science and Technology Policy.

- FDA chaired an Office of Science and Technology Policy task force charged with developing uniform cancer risk assessment procedures.

- FDA assisted EPA in the development of risk assessment and personnel exposure guidelines for microwave radiation.

- FDA and the National Institutes of Health cooperate in the development of information concerning possible risks from diagnostic use of ultrasound during pregnancy.

Question 7. Does the Office of Management and Budget ("OMB") ever comment upon or review agency risk assessments at any time during the risk assessment process? If so, at what point(s) in the risk assessment process does such OMB comment or review occur? Are any records of such comments or reviews made by the agency, and if so, are they made available to the public or the scientific community? Under what legal authority does OMB comment upon or review agency risk assessments? What is the effect of an OMB comment on or review of an agency risk assessment?

Answer. To the best of our knowledge OMB has never commented on an FDA risk assessment. At several meetings of the Interagency Risk Management Group (not the same as IRMC mentioned previously), an industry risk assessment of the color additive Red 19 was discussed. OMB officials did not comment on the actual risk assessment done on Red 19, but rather led a discussion on whether the Delaney clause should apply to a carcinogenic substance which presents a real, but small, risk of cancer.

OMB may comment upon risk assessment procedures, if the procedures are in a proposed or final rule that falls under Executive Order 12291 or are in a document containing information collection provisions that are subject to the Paperwork Reduction Act.

Question 8. Provide any written documents which refer to any procedures or understanding by which OMB comments upon or reviews agency risk assessments. Provide, for the ten risk assessments most recently completed, all written documents which make any reference to any comment, review, or contact by anyone at OMB with respect to such risk assessments.

Answer. FDA and OMB have no "procedures" or "understandings" pertaining to OMB comment upon FDA's risk assessments.

Question 9. Please indicate whether the answers to these questions have in any way been reviewed by, or commented upon, by anyone at OMB.

Answer. OMB has not reviewed or commented upon the answers to any of the questions presented herein.

Question 10. Indicate the extent to which the agency may legally be required to conduct a risk assessment, or otherwise consider risks or costs of proposed agency action, and indicate the legal authority for such requirement, whether by statute, court decision, executive order, or other authority.

Answer. FDA is not required to perform a quantitative risk assessment under any provision of a statute that it administers. The above answers to questions 1 and 2 describe when the FDA has conducted risk assessments and the statutory authority under which these assessments are done.

Attachment

RECOMMENDED FOR FULL TEXT PUBLICATION
See, Sixth Circuit Rule 24

Nos. 82-3544/3759

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

GLENN M. W. SCOTT,
Petitioner,
v.
FOOD AND DRUG ADMINISTRATION,
Respondent.

ON PETITION to Review an Order of the Food and Drug Administration.

Decided and Filed February 23, 1984

Before: ENGEL, KRUPANSKY and WELLFORD, Circuit Judges.

PER CURIAM. Petitioner, acting pro se, seeks judicial review of 21 C.F.R. 74.1205, a regulation issued by the Food and Drug Administration (FDA) authorizing the permanent listing and therefore the continued use of a color additive, D & C Green No. 5, in drugs and cosmetics.[1] This regulation was promulgated by the FDA after it determined through tests required under the Color Additive Amendments of 1960 that D & C Green No. 5, then provisionally listed, was safe for said use. Judicial review of this regulation is authorized by 21 U.S.C. § 371(f)(1), (3).

---

[1] Petitioner filed his first petition for review after the FDA announced on June 4, 1982 that it was permanently listing D & C Green No. 5. On July 1, 1982, petitioner filed objections to the order with the agency. On September 3, 1982, the FDA stayed the effect of the June 4 order as a result of these objections. On November 2, 1982, the FDA, after consideration of petitioner's objections, terminated the stay and confirmed its original order. Petitioner then filed his second petition seeking judicial review of the November 2nd order. This court ordered consolidation of the two petitions.

D & C Green No. 5 contains another color additive, D & C Green No. 6, manufactured through the use of p-toluidine, which has been proven to be a carcinogenic when tested separately, and which is present in minute quantities as a chemical impurity in D & C Green No. 5. After extensive tests, the FDA determined that D & C Green No. 5, as a whole, did not cause cancer in test animals. It also determined that p-toluidine was not itself a color additive. It concluded, therefore, that the Delaney Clause, contained in the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, regulating the use of color additives, did not bar the permanent listing of D & C Green No. 5. This clause provides:

> *A color additive (i) shall be deemed unsafe, and shall not be listed,* for any use which will or may result in ingestion of all or part of such additive, *if the additive is found by the Secretary to induce cancer when ingested by man or animal,* or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety or additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, *after tests which are appropriate for the evaluation of the safety of additives for such use,* or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal . . . .

21 U.S.C. § 376(b)(5)(B) (emphasis added).

Having found the Delaney Clause inapplicable, the FDA then evaluated the risk posed by the presence of p-toluidine in

D & C Green No. 5 under the General Safety Clause of the Food, Drug and Cosmetic Act, which provides:

> The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe . . . .

21 U.S.C. § 376(b)(4).

The FDA regulations governing approval of color additives define "safe" as meaning "that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive." 21 C.F.R. § 70.3(i).

The FDA first isolated the trace amounts of p-toluidine contained in D & C Green No. 5 and determined that the maximum life-term average individual exposure to p-toluidine from use of D & C Green No. 5 would be 50 nanograms per day. The FDA then extrapolated from the level of risk found in animal bioassays to the conditions of probable exposure for humans using two different risk assessment procedures. Under the first procedure, the upper limit individual's life time risk of contracting cancer from exposure to 50 nanograms per day of p-toluidine through the use of D & C Green No. 5 was 1 in 30 million; the second procedure resulted in a calculation of a 1 in 300 million risk. The agency concluded "that there is a reasonable certainty of no harm from the exposure to p-toluidine that results from the use of D & C Green No. 5." Fed. Reg. 24284 (1982).

Petitioner asserts on appeal that by permanently listing the color additive D & C Green No. 5, the FDA violated the Delaney Clause and the General Safety Clause of the Food, Drug, and Administration Act. Petitioner does not contest the validity of the tests employed by the FDA in determining that D & C Green No. 5 was safe for its intended uses but rather asserts that the Delaney Clause, as a matter of law, prohibits approval of a color additive when it contains a carcinogenic impurity in any amount and that the FDA has no discretion to find D & C Green No. 5 "safe" under the General Safety Clause because "[it is not] possible to establish a safe level of exposure to a carcinogen." The Agency found essentially that D & C Green No. 5, after studying the tests, did not cause cancer in test animals.

The decision of the FDA to approve permanent listing of color additive D & C Green No. 5 may be overturned by this court only if that decision was arbitrary and capricious, an abuse of discretion, or not in accordance with the law. 5 U.S.C. § 706(2)(A). The FDA's interpretation of the Food, Drug, and Administrative Act is entitled to considerable deference. *See, e.g., Hill* v. *Tennessee Valley Authority*, 549 F.2d 1064, 1070 (6th Cir. 1977), *aff'd.*, 437 U.S. 153 (1978). Even when there "is more than one reasonable interpretation of this . . . [Act], the court should follow the interpretation urged by the FDA." *United States* v. *Colahan*, 635 F.2d 564, 567-68 (6th Cir. 1980), *cert. denied*, 454 U.S. 831 (1981) (citations omitted).

We affirm the judgment of the Food and Drug Administration. Petitioner's arguments are found to be without merit. The FDA's finding that the Delaney Clause is inapplicable to the instant case because D & C Green No. 5 does not cause cancer in humans is in accordance with the law. In its final order, the FDA stated its rationale for its conclusion, and it was fully mindful of the Delaney Clause in making its decision:

> [T]he Agency does not believe that it is disregarding the Delaney Clause. In drafting the Delaney Clause, Congress implicitly recognized that known carcinogens might be present in color additives as intermediaries or impurities but at levels too low to trigger a response in conventional test systems. Congress apparently concluded that the presence of these intermediaries or impurities at these low levels was acceptable. This legislative judgment accounts for the absence of any requirement in

> the Delaney Clause that the impurities and intermediaries in a color additive, rather than the additive as a whole, be tested or otherwise evaluated for safety. Thus, Congress drew a rough, quantitative distinction between a color additive that is deemed unsafe under the Delaney Clause because it causes cancer, and an additive that is not subject to the Delaney Clause because it does not cause cancer even though one of its constituents does. FDA's decision on D & C Green No. 5 is consistent with this distinction.

47 Fed. Reg. 49678 (1982).

This interpretation of the Delaney Clause case is a reasonable one, and it is consistent with its legislative history. Congress distinguished between "pure dye" and its "impurities" in its list of factors for the FDA to consider under the General Safety Clause, but omitted "impurities" as a factor under the Delaney Clause. Although the Agency's regulatory interpretation of the Delaney Clause contains the words, "color additive *including its components*," it is clear that this regulation was aimed only at those additives containing impurities that produced cancer when tested together:

> [T]he Commissioner shall determine whether, based on the judgment of appropriately qualified scientists [from the results of appropriate tests], cancer has been induced and whether the color additive, including its components or impurities, was the causative substance. If it is his judgment that the data do not establish these facts, the cancer clause [Delaney Clause] is not applicable; and if the data as a whole establish that the color additive will be safe under the conditions that can be specified in the applicable regulation, it may be lisited for such use.

21 C.F.R. § 70.50 (emphasis added).

Since in the instant case it was determined by the FDA that D & C Green No. 5, after testing as a whole, did not cause cancer in test animals, under the plain language of the Delaney Clause and the FDA's interpretation of that Clause, the FDA was not prohibited from permanently listing D & C Green No. 5.

The FDA's conclusion that the risk levels ascertained after testing D & C Green No. 5 by isolating p-toluidine were so low as to preclude a reasonable harm from exposure to the additive, within the meaning of the General Safety Clause, is also in accordance with the law. Petitioner's assertion that the FDA has no discretion to determine that D & C Green No. 5 is safe for its intended use because it contains p-toluidine is without merit. This finding is consistent with the holding in *Monsanto* v. *Kennedy*, 613 F.2d 947 (D.C. Cir. 1979). That case involved an impurity, found to produce adverse results in test animals, present in the substance used to make beverage containers, which migrated from the container to the beverage. In discussing whether that impurity was a food additive, the court observed: "[T]he Commissioner may determine based on the evidence before him that the level of migration into food of a particular chemical is so negligible as to present no public health or safety concerns, even to assure a wide margin of safety. This authority derives from the administration discretion, inherent in the statutory scheme, to deal appropriately with *de minimus* situations." *Id.* at 955 (see n.26 at 995 for list of case authority supporting the court's observation.)

We find this determination by the *Monsanto* court persuasive and relevant to the particular facts of the instant case. We agree with the FDA's conclusion that since it "has discretion to find that low-level migration into food of substances in indirect additives is so insignificant as to present no public health or safety concern . . . it can make a similar finding about a carcinogenic constituent or impurity that is present in a color additive." 47 Fed. Reg. 24280 (1982). Accordingly, we hold that the FDA did not abuse its discretion under the General Safety Clause in determining that the presence of p-toluidine in D & C Green No. 5 created no reasonable risk of harm to individuals exposed to the color additive.

The decision of the FDA to permanently list D & C Green No. 5 is hereby AFFIRMED.

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

May 15, 1984

Honorable James H. Scheuer
Chairman, Subcommittee on Natural Resources,
  Agriculture Research, and Environment
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed is in response to your letter requesting information regarding risk assessments. After we received your request, Mr. Bobby Acord of our staff discussed the matter with Mr. Michael Rodemeyer. They agreed that our response would address only risk assessment activities and procedures of the Food Safety and Inspection Service and that that information would suffice for the purposes of the committee's May 17 hearing.

Sincerely,

John R Block

Enclosure

FSIS RESPONSE TO QUESTIONS SUBMITTED BY CHAIRMAN JAMES H. SCHEUER

1. List and briefly describe, all uses of risk assessment within the agency.

FSIS usually depends on FDA for decisions on the safety of food substances and animal drugs and limits its own risk analyses to issues involved in the conditions of use of these susbstances in meat and poultry products. FSIS also depends for the most part on FDA and EPA for decisions on the acceptable level of hazardous substances which FSIS implements through tolerances or action levels. Therefore, FSIS is not called upon to perform the kind of risk assessment involving less well-defined biological and chemical phenomena and the transference of knowledge on such phenomena from animals to human situations and from high-to-low dose situations that is the character of risk assessment as described in H.R. 4192.

There are, however, some areas where FSIS employs risk assessment to determine whether a public health risk exists or to determine level of exposure. The following examples illustrate this type of FSIS activity.

- In making regulatory decisions, FSIS will sometimes make use of expert panels which are convened for the specific purpose of assessing risk. Panels have been convened to assess the safety of products made by mechanical deboning and the safety of cured products containing nitrosamines.
- For informational purposes related to determining the need for regulations, FSIS will sometimes monitor the level of a particular substance in meat and poultry products. The Agency is currently conducting a sodium monitoring program. In 1983 the Agency analyzed 300 samples to determine whether EDB was present in meat and poultry.
- FSIS will conduct research to determine the safety of a product. The Agency recently completed animal feeding studies to assess the risk from various sizes of bone particles.

The above examples are all focused on developing better information for regulatory decisions. The Agency also employs risk assessment principles in the day-to-day management of the inspection program.

FSIS managers employ risk assessment principles on a daily basis in their decisions concerning the allocation of the Agency's field inspection resources. In a recent publication entitled, "Protection and Productivity: The Strategy for Meat and Poultry Inspection in the 1980's," FSIS identified four principles that have guided recent changes in the meat and poultry program. One principle is that the allocation of inspection resources should be based on the risks to the public inherent in a product, a process, or a producer.

In that same publication the Agency identified the following element as a key component of its future strategy in residue control programs:

- THE **EXPANDED USE OF RISK ASSESSMENT PRINCIPLES,** INFORMATION SYSTEMS, AND IMPROVED TESTING METHODS WILL SIGNIFICANTLY INCREASE THE ABILITY TO ADDRESS RESIDUE PROBLEMS.

  -Risk assessment will be used to determine FSIS' testing agenda. Setting priorities will considerably enhance the effectiveness of the program by ensuring that FSIS monitors and controls those compounds that are most hazardous. Compounds are being ranked on the basis of:

  --the amount of actual or probable use,

  --the conditions of use,

  --any potential misuse of a substance, and the likelihood of adulterating residues, and

  --the toxicity of the residue and the severity of any human effects from adulteration.

-Risk assessment will be used to evaluate actual consumer exposure to residues in meat and poultry, combining monitoring information and food intake information.

The use of risk assessment as described above is the evolution of a practical management strategy. The Agency has long recognized that it cannot test for every chemical substance that might find its way into the food supply. The Agency's residue monitoring program allocates its resources based on criteria such as the use of the substance in agriculture production practices and the likelihood that the susbstance could be found in the animal food supply.

2. **Indicate the total number of "risk assessments" completed and in progress during the last twelve months. For such "risk assessments," indicate the total cost to the Agency, including separate figures for staff resources and consultant or contractual expenses incurred.**

FSIS does not as a matter of course, produce formal written risk assessments containing the level of detail and analysis envisioned in H.R. 4192. FSIS depends on FDA for decisions on the safety of food substances and animal drugs that require complex risk assessment. The type of "risk evaluation" that occurs within FSIS is an integral part of the day-to-day management of the inspection program (see section I), and is, therefore, impossible to cost out separately from our other inspection activities.

In the last 12 months the Agency did issue contracts for rodent feeding studies to help identify any potential risks associated with certain sizes of bone particles. The variables in these studies were well-defined and it was not necessary to conduct a complex risk assessment for these tests.

3. **Indicate the extent to which risk assessments conducted by the agency include the elements set out in Sec. 107(a) of Title I of H.R. 4192.**

In general, the FSIS activities described in Section (1) will not include the elements of Sec. 107(A) as they are usually handled in a risk assessment context. However, elements of risk are frequently addressed in preambles to FSIS regulatory proposals and in the regulatory impact analyses conducted under Executive Order 12291. For example, FSIS is frequently concerned about a risk to a particular segment of the population, such as children or people on special diets. The Agency will also address the roles of technical or scientific advisory boards in preambles along with discussions concerning the limitations on information or scientific uncertainties. The Agency will also discuss alternative courses of action, but, as mentioned in Section (1), these analyses more often concern less complex issues of public health than those associated with risk assessments as described in H. R. 4192.

4. **Indicate the extent to which the agency makes its risk assessments and any guidelines under which risk assessments are prepared, available to the public or to the scientific community.**

All information used to develop FSIS regulatory proposals is made available to the public.

5. **Describe any efforts the agency has made within the last two years to improve or expand the use of risk assessment within the agency, including any efforts to improve intra-agency coordination of risk assessments or the development of any guidelines or protocols for risk assessments.**

See discussion in Section (1) above.

FSIS scientific personnel work closely with the FDA and EPA personnel involved in setting tolerances or action levels for various chemical substances.

6. **Describe any efforts the agency makes to coordinate its risk assessments or its risk assessment procedures with other federal agencies.**

FSIS has Memorandums of Understanding (MOU) with both FDA and EPA that address coordination of residue control programs. There is currently an effort underway to develop a single three-agency MOU. These MOU's address tolerances, action levels and their implementation.

7. **Does the Office of Management and Budget ("OMB") ever comment upon or review agency risk assessments at any time during the risk assessment process? If so, at what point(s) in the risk assessment process does such OMB comment or review occur? Are any records of such comments or reviews made by the agency, and if so, are they made available to the public or the scientific community? Under what legal authority does OMB comment upon or review agency risk assessments? What is the effect of an OMB comment on or review of an agency risk assessment?**

Under Executive Order 12291, OMB reviews all FSIS regulations and analyses. All FSIS risk assessment elements are covered in these documents, but these are usually less complex and less controversial than the risk assessments discussed in H.R. 4192 and, therefore, do not attract attention from OMB.

8. **Provide any written documents which refer to any procedures or understanding by which OMB comments upon or reviews agency risk assessments. Provide, for the ten risk assessments most recently completed, all written documents which make any reference to any comment, review, or contact by anyone at OMB with respect to such risk assessments.**

Not Applicable

9. **Please indicate whether the answers to these questions have in any way been reviewed by, or commented upon, by anyone at OMB.**

Not applicable.

10. **Indicate the extent to which the agency may be legally required to conduct a risk assessment, or otherwise consider risks or costs of proposed agency action, and indicate the legal authority for such requirement, whether by statute, court decision, executive order, or other authority.**

The meat and poultry inspection acts do not permit any substance to be present in meat and poultry if that substance presents a threat to human health. As stated earlier, FSIS usually relies on FDA or EPA to conduct the risk assessment necessary to establish tolerances or action levels. In other cases, the Agency is responsible for conducting the necessary studies to determine if products or ingredients are safe and wholesome. If the Agency determines that products or ingredients do, in fact, pose a threat to human health, then that product or ingredient must be prohibited from entering human food channels. In those cases, the Agency cannot weigh risks and benefits or make decisions based on a cost-benefit analysis. In any case, however, the Agency will always conduct the necessary regulatory impact analysis as required under Executive Order 12291.

○